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Translation, Validation and Comparison of Three
Behavioural Pain Assessment Tools for Patients
who cannot Communicate Verbally

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Abstract

Aim

The thesis set out to examine validations of three observational pain assessment tools and establish nurses' expectations of them and the factors that might influence them within intensive care unit (ICU) settings.

Background

The guidelines to pain assessment specific to ICU patients have been of great interest to health professionals over the last 20 years. Pain assessment remains a challenge for most ICU patients due to the difficulty of assessing pain with any precision. Evidence suggests that the Behavioural Pain Scale (BPS) and Critical-Care Pain Observation Tool (CPOT) have demonstrated sound psychometric properties. A review of the relevant literature highlighted the fact that no such studies have yet been conducted with a similar homogenous group in Asia. The Wong-Baker Face Pain Rating Scale (FPRS) is currently widely used for nonverbally communicating patients (NVCPs) with pain in ICU settings, and is even recommended for use with children. Valid assessment tools are required for effective pain assessment in ICU settings, particularly in patients who are experiencing communication difficulties.

Design

An embedded mixed methods design was employed to: 1) translate Chinese versions of BPS and CPOT, 2) test their validity and reliability of in comparison with FPRS, and 3) establish the nurses' expectations about the three study scales when undertaking pain assessment by using semi-structured focus group interviews.

Methods

This thesis initially reviews the literature available to select the most appropriate scales for assessing pain in critically-ill NVCPs. The selected scales were then translated into a Traditional-Chinese version using established procedures for the Taiwanese context. Evaluations of the three pain scales were gathered using quantitative measures of pain scores in NVCPs experiencing painless/painful interventions. These were further compared with a few focus groups to establish the feasibility and utility of the three pain scales.

The psychometric properties of the pain scales were assessed for reliability by using internal consistency and inter-rater agreement) and for validity by using content validity, concurrent validity, discriminant validity, and responsiveness. The validity was evaluated using ANOVA to compare the changes between the different procedures. The significance level was set at 0.05. As for the analysis of the qualitative data, this study typically follows the path of aggregating the words into themes of information and presenting the diversity of ideas gathered during the data collection.

Results

For the 2068 observations in 237 patients, there were no statistical differences between the characteristics of the BPS, CPOT, and FPRS groups. Validity was demonstrated by changes from baseline in the scores of the three groups, which were significantly higher during suction ($p < 0.001$). In regard to the result for the criterion validity, both BPS and CPOT had moderate positive correlations with FPRS. The internal consistency was excellent; the Cronbach's α was 0.700 for BPS and 0.821 for CPOT when all items were included.

The majority of nurses preferred to use BPS to assess pain in their clinical practice. When the nurses were asked how long they needed and how easy they found it to complete the assessments using these tools, they all agreed that each patient assessments were easier and took the least time when they used FRPS. However, the nurses considered that the most effective pain reaction during nociceptive procedures had been assessed by using BPS. Even though all of the participant nurses stated that CPOT provides a detailed item-description about pain behaviour, it also provided the biggest obstacle to use because of its ambiguous indicators.

Conclusions

BPS, CPOT and FRPS provide potentially useful measurement scales for assessing pain in ICU NVCPs. However, judging from the inconsistencies between the nurses' replies, the results could reflect a conflict between the need to use a validated measure of pain for NVCPs on the one hand and managing a heavy workload in the ICU on the other. This study opens up an avenue for investigating further the link between the underlying conceptions of pain behaviour and the effectiveness of pain assessments in NVCPs when using an objective pain measurement.

Lay Summary

Guidelines to assess pain have been of great interest to health professionals over the last 20 years. Rating pain remains a challenge within the health care profession. Current research suggests that two scales; Behavioural Pain Scale and Critical-Care Pain Observation Tool are excellent ways to measure pain. The Wong-Baker Face Pain Rating Scale is currently widely used for patients who cannot talk about their pain when in the hospital. The study set out to examine the use of these three pain assessment tools in the intensive care setting to try to understand the nurses' thoughts and feelings about their use.

Based on experts' suggestions, this study used a four-stage method to translate the pain scales into a Chinese version. After receiving approval from the board of research ethics, all three pain scales were tested in a sample of 169 patients who could not speak by 11 nurses. The nurses rated pain behaviours and the intensity of those behaviours on the patients using the three pain scales for different medical procedures. Finally, the nurses were interviewed to assess their overall opinion of the three pain scales.

The three pain scales each provided a useful method for assessing pain in patients that cannot speak when they are in the hospital. This study highlights the importance for clear ideas of pain behaviours and the most reliable ways to rate pain for patients that cannot speak for themselves.

Key Words

Validity, Pain measurement, Scale Development, Critical care, Mixed methods

Word count: 63,560

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Declaration

I hereby declare that this thesis has been composed by myself and has not been submitted in any previous application for any degree. I have not copied from any other students' work or from any other sources except where due reference or acknowledgement is made explicitly in the text, nor has any part been written for me by another person. Any editorial work, paid or unpaid, carried out by a third party is acknowledged and ethics procedures and guidelines have been followed.

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GLOSSARY

--Explanations of medical terms and abbreviations are provided in the Glossary.

Term/Abbreviation	Explanations
Analgesic	Any member of the group of drugs used to achieve analgesia — relief from pain.
Anesthesia	A temporary state consisting of unconsciousness, loss of memory, lack of pain, and muscle relaxation.
Benzodiazepines	A class of psychoactive drug.
Coma	A state of unconsciousness lasting more than six hours.
Construct validity	The degree to which an instrument measures the construct under investigation.
Content validity	The degree to which the items in an instrument adequately represent the universe of content for the concept being measured.
Criterion validity	The degree to which scores on an instrument are correlated with some external criterion.
Cronbach α	Measures the extent to which items go together and identifies those items that contribute little to the overall measurement score.
Delirium	An organically-caused decline from a previously attained baseline level of cognitive function, typified by a fluctuating course, attention deficit and generalised severe disorganisation of behaviour.
Dementia	A brain disease that causes a long term and often gradual decrease in the ability to think and remember such that a person's daily functioning is affected.
Discriminant validity	An approach used to construct validation that involves assessing the degree to which a single method of measuring two distinct constructs yields different results.
Electrocardiography	A process of recording the electrical activity of the heart over a period of time using electrodes placed on a patient.

Term/Abbreviation	Explanations
Endotracheal	The insertion of a catheter and the removal of secretions from an artificial airway, using a suction device attached to a negative pressure vacuum setup.
Fentanyl	A potent, synthetic opioid analgesic with a rapid onset and short duration of action.
Haemodynamically	Relating to the flow of blood within the organs and tissues of the body.
ICU	Intensive Care Unit
Interrater reliability	The degree to which two raters or observers, operating independently, assign the same ratings or values for an attribute being measured or observed.
Internal consistency	The degree to which the subparts of an instrument are all measuring the same attribute or dimension, as a measure of the instrument's reliability.
Intubation	The insertion of a tube for medical reasons, usually with anesthesia. Examples include tracheal intubation.
Item to total correlation	A statistical procedure to identify items in a scale that are not related to the other items in the scale.
Mechanical ventilation	A method for mechanically assisting or replacing spontaneous breathing.
Mean arterial pressure (MAP)	A term used in medicine to describe average blood pressure in an individual.
Midazolam	A drug used to treat acute seizures and moderate to severe insomnia, as well as inducing sedation and amnesia prior to medical procedures.
Neuromuscular blockers	These block neuromuscular transmission at the neuromuscular junction, causing paralysis of the affected skeletal muscles.
Nonparametric statistics	Statistical procedures for analysis of data that do not meet the assumptions for parametric statistics (i.e., are not randomly selected) at the interval or ratio level of measurement or are not normally distributed/are skewed.

Term/Abbreviation	Explanations
NVCP	Non-verbally communicative patients. Patients unable to communicate verbally or respond in any manner due to mechanical intubation, sedation, or unconsciousness.
Peripheral neuropathy	A disease affecting the nerves, which may impair sensation, movement, gland or organ function.
Psychometrics	The assessment of psychological variables through the application of mathematical procedures.
Propofol	A short-acting, intravenously-administered hypnotic/amnestic agent.
Quadriplegic	The partial or total loss of use of limbs and/or torso in humans due to illness or injury.
Registered nurse (RN)	A nurse who has graduated from a nursing program and successfully passed the certification exam.
Reliability	The overall consistency of a measure.
Sedation	An induced state of sleep or rest through drugs.
Sensitivity	The ability of screening instruments to correctly identify a “case,” that is, to correctly diagnose a condition.
Staff nurses	These nurses are responsible for a set group of patients to which they are responsible (e.g. administering medications, assessing, wound care and other clinical duties).
Stroke	Apoplexy, a sudden weakness often on one side of the body, caused by a disruption to the blood flow in the brain.
Tetraplegia	See quadriplegia.
Unconsciousness	A state which occurs when the ability to maintain an awareness of the self and one’s environment is lost.
Validity	The extent to which a concept, conclusion or measurement is well-founded and corresponds accurately to the real world.
Ventilator compliance	A patient’s capacity to yield to pressure from an expression of the distensibility of mechanical ventilation.
Wilcoxon signed rank test	A nonparametric statistic to test for differences between two matched pairs of ranked samples; comparable in use to the paired t test for parametric data.

CHAPTER 1 Introduction

1.1 Introduction

The following work describes quantitative and qualitative enquiries into the experiences of nonverbally communicative patients in intensive care units (ICUs). Patients' experience of pain during critical illness and nurses' perceptions of patients' pain within this environment are not well understood. Pain remains a subjective experience, while objective measures are applied in order to maximize pain management. The dichotomy between the subjective and objective experience of both the pain sufferer and the health care professional is of investigative interest.

This research explores the typical early pain assessments of patients with critical illness and the various pain assessment scales currently in use. Of significant importance to the objective measurement of pain is the skill of observation amongst the nurses and the scales used in practice on the ward. This study focuses on the group characterised as nonverbally communicative patients (NVCPs) with critical illness. The importance of accurate pain assessment and need for a valid and reliable pain scale for use in patients who are unable to communicate are crucial for effective pain treatment management.

1.2 Rationale of the research

The rationale for this study is based on the experiences of the researcher as a nurse and clinical instructor in ICUs in university hospitals in Taiwan. Through taking observations over a number of years, it has been noted that patients are at high risk of suffering due to unrecognised and under-treated pain when critically ill. A valid

method for documenting pain would further the effective treatment of pain (Carr 2007). Currently, pain assessment is based on the observation of facial expressions. Health professionals are trained in the use of the Facial Pain Rating Scale (FPRS) and treatment plans are based on the scores as observed by the health caregiver. This scale has been accepted for use in Taiwan for both paediatrics and NVCPs (Li et al. 2007). The use of FPRS as an accepted means of rating pain in conjunction with observations of physiological changes (i.e. increased blood pressure) has been shown to provide an inaccurate assessment of pain (Arbour & Gélinas 2010). Due to the inherent assumptions of pain experience, FPRS can be misleading, as can physiological parameters. When the nursing staff focuses exclusively on acute physiological changes in patients, errors in pain treatment planning can result. The problem of inaccurate pain assessment is magnified in patients who are unable to communicate their discomfort directly. Critically ill patients experiencing high levels of pain are at risk of a variety of negative psychological and physiological consequences. This lack of knowledge with respect to the patient's perception of pain is the rationale for selecting and refining an appropriate tool for accurately assessing pain in patients who lack the ability to report their pain verbally. In doing so, an in depth understanding of pain-induced physiological changes and behaviour will allow for more accurate assessments and effective treatment plans.

1.3 Research background

The pathology and aetiology of pain are among the most difficult issues to investigate. A systematic approach to pain assessment is critical for optimal pain management. The gold standard of pain assessment remains patients' self-report. However, this is impossible when assessing or treating NVCPs. The blurred

boundaries between physical symptoms and subjective experience are particularly apparent in pain perception. This makes the current biomedical approach ineffective. The search for an explanation of how to control this phenomenon within a biopsychosocial framework becomes imperative. Self-reported pain assessment in NVCPs is impossible to undertake, as these patients are unable to communicate verbally. The necessity for integrative efforts, both theoretical and empirical, is evident given the proliferation of research and intervention programmes available.

For many people, critical illness poses a challenge with regard to many domains of their lives. Pain is a common, distressing symptom in critically ill patients. A systematic assessment of pain is difficult in ICUs due to the high percentage of NVCPs present. Several tools have been developed to identify objective measures of pain, but there are currently no recommendations that identify which assessment tool is most appropriate for use with this patient population. A comprehensive literature search was completed to identify relevant evidence pertaining to the reliability and validity of the available observational pain scales (Pudas-Tahka et al. 2009). Although the evidence was evaluated and synthesised to identify the ideal instrument for assessing pain, its accuracy remains questionable due to the problematic study design or a small sample size.

In recent years, regulatory agencies have focused on the identification and treatment of pain (Herr et al. 2006). This is part of the impetus behind the development of behaviour-based pain scales to assess pain in NVCPs (Pasero & McCaffery 2005). The tools are based on the identification of behaviour such as facial expressions, vocalisation, withdrawal reflexes and other motor movements, which are associated

with the existence of pain (Cade 2008). Pain awareness dominates the individual's consciousness to such a degree that the constant exposure to this phenomenon blurs the boundary between psychological and physical suffering. This often defies efforts to manage the condition. The all-encompassing nature of pain leads to major difficulties related to research in this area. Due to the subjective nature of pain and the objective nature of the observation of pain, it is extremely difficult to rate pain accurately. The difficulty in rating pain in a reliable, valid manner becomes an even greater challenge in patients who are unable to communicate their distress. Reliably identifying pain in patients who are incapable of spontaneous neuromuscular movements or in those with concurrent conditions (i.e. delirium, dementia, and coma) is often the difficult task facing nurses in ICUs (Achterberg et al. 2013, Puntillo 2007). The challenge of accurately assessing pain in NVCPs is an important variable in the formulation of effective pain management plans.

1.4 Purpose of the thesis

This research attempts to assess the reliability and validity of pain behaviour assessment tools as established in recent empirical studies (Gelinas et al. 2006, Payen et al. 2001, Wong & Baker 1988). This thesis examines the strategies for improving the pain assessment practices in ICUs. Of key importance are the education of ICU nurses and the application of a valid, reliable assessment scale to improve patients' pain management. In part, this thesis is an examination of the current tools available for assessing pain in the critically ill patient who is unable to communicate. This will then establish the nurses' expectations of these tools and the factors that might influence their choices within ICU settings

Patients who are being treated with sedation and mechanical ventilation are the focus group of this research. The accurate analysis of the data supporting the reliability and validity of these pain scales is of extreme importance. Practicality and feasibility will also be explored by using focus group discussions to interview the users of the pain scales. Each instrument is described, and a subsequent evaluation of the available relevant evidence is provided. Relevance is based on the study design and methods, sample, theoretical foundation (if any), major findings, and limitations. Based on the findings of this analysis, a comprehensive synthesis of the evidence is described. Thereafter, gaps in the literature are identified and discussed. Finally, implications for future research aimed at improving the understanding of pain assessment in NVCPs are outlined.

1.5 Research context

The study took place in four teaching hospitals and a medical research centre. Eight units were involved in the study, all of which were medical/surgical ICU settings with over 20 beds each. The patient and nurse recruitment for the study was confined to these eight units. The study took place over an 18 month period.

The Taiwanese population is densest in the Taipei metropolitan area (northern Taiwan) and Keelung, with a third of the country's population being located in this region alone. Taichung and Hualien (central Taiwan), and Chia-Nan and Kaohsiung (southern Taiwan) account for the remaining spread of the population (Department of Statistics 2012). Participant recruitment for the study was confined to the 5 health care services, which are distributed across the north, centre, and south of Taiwan.

The official national language is Mandarin using Traditional Chinese text, although the majority also speak Taiwanese and Hakka.

Taiwan legislation mandates minimum nurse-to-patient ratios in hospitals. The ratio in ICUs should not fall below one nurse per every two patients (Herdman et al. 1997). However, this minimum ratio (one nurse: two patients) has not been fully implemented in Taiwan and only applies to daytime shifts. Currently, the inadequate nurse staffing ratios lead to there being two or three patients per nurse in ICUs (Department of Health 2012a). This leads to a higher nursing workload which may increase patient mortality (Galley & O’Riordan 2003). Unfortunately, the pain assessment tools available to Taiwanese nurses rely on self-report (i.e. the Numerical Pain Scale, NPS). The currently preferred and validated scale for pain assessment with Chinese NVCPs is the Wong-Baker FACES Pain Rating Scale (FPRS) developed for child pain assessment (Li et al. 2007). Neither NPS nor FPRS, as they are currently implemented in Taiwanese ICUs, are sufficient for assessing pain in NVCPs.

1.6 Structure of the thesis

The structure of this thesis is affected by two primary characteristics of this research. It involves a literature review to identify the relevant pain scales and the adoption of a mixed research approach to explore the selected scales. The principle of sequential mixed methods is that the findings of phases 1 and 2 inform phase 3. No expectations for phase 2 may be developed until phase 1 has been completed. Secondly, the exploratory nature of the research requires that no assumptions are made such that the findings remain unbiased. To remain true to the methodology,

the thesis consists of two parts, each of which reflects a specific research phase. Part 1 is the selection of the pain scales. Part 2 begins with phase 1, which is a qualitative study to explore the content validity and develop the assessment tool requirements to support acceptable and feasible use in the context. This phase also employed a pilot study to validate the use of the Chinese versions of the pain scales. Following phase 1, phase 2 is the full study designed to evaluate and compare both the reliability and validity of the study instruments. Phase 3 is also a qualitative study to establish the nurses' expectations of them and the factors that might influence them within ICU settings. Focus groups and in-depth interviews are conducted.

Part one begins with the second chapter of the thesis, which reviews the literature relevant to the research. According to the literature, the pain scales of interest will be selected for study and determine the choice of study instrument for the research. Chapter 2 provides an epidemiology of pain and assessment in critically ill patients. The current theories with respect to the physiological mechanisms and experience of pain are explored. In particular, the many different tools for assessing pain, which are utilised in many ICUs, will be discussed. The benefits, design, implementation, validation and reliability of these pain assessment tools will be briefly reviewed, and their use in the ICUs of Taiwanese clinical practices will be of considerable interest.

Based on the current knowledge in the field of pain assessment scales for NVCPs, the methodology and theoretical framework that underpins it will be developed and discussed in Chapter 3, which outlines the mixed methods design employed for the

three phases of this qualitative and quantitative research model. The ethical considerations of this research are also provided in this chapter.

Chapter 4 presents the initial phase of the second part of the study. A background of how the measurement tool to be developed for use in another clinical practice is described in Chapter 4 (Section 2). This will also incorporate the translation and validation via pilot study of the selected pain scales. Literature relating to the development of the method for translating pain scales with cross cultural awareness and evaluation is presented in this chapter. Analyses of adjustments to the terms of the psychometric properties of the study instruments under investigation are also presented in this chapter.

Chapter 5 presents a critical appraisal of the validity and reliability of the selection of the pain scales that are of research significance. The qualitative aspect and its validity is based on nursing experiences with NVCPs. It argues that previously tested surveys provide a reasonable foundation on which to structure the interview questions. The data collection and sample characteristics from phase 2 are presented, along with the results of the data analysis.

Chapter 6 establishes the basis for the focus groups arising from the findings in phase 2. Literature on the development of the focus group is presented. This chapter also describes the process of data collection for qualitative aspects in this phase, which employed first-hand reports based on the nurses' experiences.

Chapter 7 brings together the theoretical and empirical findings to offer interpretations of the multiple results via quantitative and qualitative approaches.

Statistically significant results are highlighted in addition to interesting trends. The results are explored in a systematic manner.

Chapter 8 concludes and reflects upon the research carried out, together with its limitations. The research questions are answered and recommendations are made. The research aims accurately to inform, via quantitative and qualitative assessment, the manner in which NVCPs experience pain and also to act as a guideline for improved pain management. The literature remains sparse with respect to the experience of pain in NVCPs and, as such, this research may in part serve to increase our understanding of this phenomenon.

CHAPTER 2: Literature Review

2.1 Introduction

The previous chapter highlighted the lack of pain assessment tools for NVCPs in ICUs. The literature review has shown that few validated and reliable behavioural pain assessment tools exist. Currently, there is a lack comparative studies which examine the reliability and validity of the behavioural pain assessment tools. Moreover, the psychometric testing of these tools has rarely been specifically investigated with Asian populations.

The intention of this literature review is to critically examine the literature related to patients' pain experiences with critical illness. Pain assessment during patients' hospitalization in ICU settings and the understanding of their pain within the context of NVCPs is challenging for ICU nurses. This literature review is preparation for further interpretation of the data in later chapters. The main focus of this review is pain management, with specific attention to unconscious or sedated patients with mechanical ventilation within ICU settings. The focus of this chapter is on reviewing the theory of pain in ICU setting to identify the current issues nurses face when gauging pain in this patient group. Included in this section is a critical evaluation of the current issues of pain assessment and the barriers to pain assessment specifically related to sedated and ventilated patients. Secondly, this review critically explores the current literature investigating the validity and reliability of objective pain measurement in NVCPs. This informs the critical discussion highlighting the need to develop simple, practical pain assessment tools

in ICU nursing practice. This review of pain assessment for NVCPs may provide a more comprehensive basis for enhancing pain management in ICU settings.

2.2 Definition of pain

Pain is always subjective. “Pain is whatever the experiencing person says it is, existing whenever he/she says it does” (McCaffery 1968). This is an interesting definition of pain for someone who is able to communicate and articulate what their pain level is- however it is not the best definition for those who are unconscious or unable to express their pain experience (Pasero & McCaffery 2011). A comprehensive definition of pain needs to address all concepts acknowledging a combination of the physical, psychosocial and subjective concepts associated with pain.

The experience of pain is complex, subjective experience that involves sensory, emotional and behavioural factors associated with tissue injury. The International Association for the Study of Pain (IASP) pain can be defined as pain can be defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk 1994). This is a global all-encompassing definition concerning physical, psychological and emotional aspects of pain. Pain is not a directly observable or measurable phenomenon, but rather a subjective experience that bears a variable relationship with tissue damage (Merskey & Bogduk 1994). The task of health caregivers is to identify how the individual’s pain behavioural might be used to reflect the individual's experience of pain.

Nurses have a fully informed picture when assessing a patient's pain and requires them to use a biopsychosocial approach for assessment and treatment of pain (Gordon et al. 2005). Pain can present a challenge to nurses because it may have an unclear cause, and not respond well to the normal pathways of treatment. When pain is initiated or caused by a primary lesion, it stimulates the normal response to noxious injury of tissues and result in activation and sensitization of pain pathway by a variety of mediators released at a site of tissue inflammation (Kidd & Urban 2001). Pain perception is a complex process involving sensory impulses from the "pain gate" (Melzack R & Wall 1965) and activation of responses via the limbic and autonomic nervous system to develop a pain experience that includes emotional and subjective sensory components (Anaesthesia UK 2004).

The physiological responses that take place via the sympathetic nervous system and the neuro-endocrine system are numerous and intrinsically linked. When the patient suffers pain, increasing activity in the sympathetic nervous system causes the brain to release endorphins to relieve the pain. Consequently there is an increase in the basal metabolic rate, which impacts the physiological responses, such as the cardiovascular, gastrointestinal, respiratory, and genitourinary (Middleton 2003, Porro et al. 1999). Table 2.1 presents the impact that unrelieved pain may have on physiological changes in the body's systems (Middleton 2003). The physiological changes that take place, if left untreated can lead to chronic pain conditions. Adverse effects of unrelieved pain on psychological and cognitive functions are also relatively common (Well et al. 2008).

Table 2.1 Effects of physiological changes from unrelieved pain

Physiological response	Increase	Decrease	Reasons
Cardiovascular system	1. Heart rate 2. Blood pressure 3. Peripheral vascular resistance 4. Oxygen consumption		Increasing sympathetic nervous system activity
Gastrointestinal system		Mobility of gastrointestinal (GI) tract	Increasing sympathetic nervous system activity
Respiratory system	Inspiratory and expiratory pressures	1. Vital lung capacity 2. Alveolar ventilation	limiting the movement and reflex muscle spasm
Genitourinary system	1. Fluid overload, 2. Cardiac workload 3. Blood pressure		Urinary retention caused by increase the release of hormones and enzymes.
Musculoskeletal system		Immobility	Impaired muscle function and muscle fatigue

Unrelieved pain may have an effect various physiological signs and parameters; therefore the accurate assessment of such a stress response is vital. This emphasises the need for appropriate assessment and management of pain when caring for unconscious patients and individuals with impaired communication skills due to disease or language barriers, as well as those who do not possess a command of the caregiver's language (Craig, 2006). Good acute pain assessment, including an

understanding of the physiological effects of pain, is an essential element of holistic nursing care (Pasero & McCaffery (2011).

2.3 Pain in patients with critical illness

Globally, more than 5 million people are admitted to ICUs suffering critical illness annually (Garland et al. 2013). An estimated 71% of these patients recall experiencing pain during their hospital stay (Klein et al. 2010). Pain is one of the most common symptoms present in the critically ill and is experienced uniquely by each patient (Puntillo et al. 2010). Critically ill patients are predisposed to experiencing pain due to both the nature of their pathophysiologic process (Blakely & Page, 2001) and the therapies and procedures that they undergo (Summer & Puntillo 2001). Painful procedures, such as turning, tracheal suctioning, catheter insertion and sheath removal, are performed commonly in ICUs, and can lead to acute pain (Cade 2008, Chanques et al. 2007, Puntillo et al. 2001). In addition, many critically ill patients have a history of chronic pain, which further complicates their assessment and treatment (Curtiss & McKee 2004). When pain is present in critically ill patients, it is more likely to be of moderate to severe intensity and multidimensional in nature (Puntillo et al. 2010).

Untreated pain can result in negative consequences, including multisystemic complications and the development of chronic disabling pain. This has the capacity to seriously impact the patient's functioning, quality of life, and well-being (Dunwoody et al. 2008). Furthermore, the absence of, or inaccurate assessment of pain has been associated with increased morbidity and mortality in ICUs.

2.3.1 Impact of pain in ICU patients

Acute pain remains a serious problem, even when patients report moderate satisfaction with their pain management (Tocher et al. 2012). Over 80% of the world population experiencing physical pain do not have access to appropriate analgesia (Scholten et al. 2007). The World Health Organization (WHO) estimates that 83% of the world's population with moderate to severe pain are suffering due to inadequate treatment (Seya et al. 2011). Many critically ill adult patients experience significant pain during hospitalisation. In ICUs, more than 30% experience significant pain at rest and more than 50% during routine care.

Each patient experiences pain in a unique manner, despite being one of the most common symptoms present in the critically ill (Puntillo et al. 2008). A predisposition to pain is based on the physiological mechanisms and diseases of critically ill patients. (Blakely & Page 2001) The impact of therapies, and daily interventions as invasive procedures, also affect patients' pain load (Cade 2008, Summer & Puntillo 2001). These invasive procedures are required to maintain as well as monitor patients' haemodynamic stability or respiratory compromise.

Pain may be a result of the events that led to patients' admission to ICU, as well as directly related to their critical care management while hospitalized. Unfortunately, acute and critically ill patients are regularly exposed to many forms of therapeutic or diagnostic procedures, which further initiate painful and/or distressing experiences (Arroyo-Novoa et al. 2008, Kress 2007).

Pain is a common stressor in ICU settings and high rates of untreated pain remain common in the critically ill (Campbell & Happ 2010). Untreated pain has been associated with a variety of psychosocial effects, including depression, anxiety, delirium, post-traumatic stress disorder and disorientation (Jacobi et al. 2002). An unmodified, prolonged stress response (untreated pain) has undesirable long-term effects on regional ischaemia, immune function and catabolism (Blakely & Page 2001, Rainville et al. 2005). Pain results in serious implications for a critically ill patient. They may have increased oxygen requirements due to pain and require isotropic medication to support blood pressure, which improves heart contractility. The presence, intensity of or absence of pain will have significant effect on the treatment planning and management of critically ill patients. Thus, it is vital to improve pain assessment and treatment in critically ill patients.

2.3.2 Sources of patients' pain in critical care

The atmosphere within ICUs is stressful for patients, their families, and the health care staff (Heather 2010). Stress has the potential to increase the perceptions of patients, while simultaneously reducing the nurses' awareness of the patients' pain relief needs. Pain may be a result of the events that brought the patients to the ICU, as well as a result of their critical care management. Acutely and critically ill patients are exposed to many therapeutic or diagnostic procedures that contribute to their pain and/or distress (Arroyo-Novoa et al. 2008, Kress 2007). ICU patients experience pain and physical discomfort due to several factors, such as; pre-existing disease, trauma, invasive procedures (insertion of endotracheal tubes, invasive monitoring lines, central venous catheters, chest drains, and dialysis catheters), or routine nursing care (airway suctioning,

physical therapy, dressing changes, and patient mobilisation) (Jacobi et al. 2002, Puntillo et al. 2004).

In ICU settings, many sedated and intubated patients are unable to communicate their experience of pain. They cannot communicate verbally or by pointing at visual pain scales, making pain assessment particularly difficult in this patient group (Kwekkeboom & Herr 2001, Jacobi et al. 2002, Aslan et al. 2003). Observing the behaviour affected by the pathology is a potential indicator of pain. In Melzack's (1983) seminal work, key skills were identified to ensure successful pain assessment, highlighting the need to understand the mechanisms of pain and the ability to evaluate the methods used for pain relief.

2.4 Pain Assessment in ICU non-verbally communicative patients (NVCPs)

The primary obstacle of successful pain management is the inability to assess pain accurately from an objective perspective (Odhner et al. 2003). Pain assessment is particularly difficult in NVCPs as the most reliable indicator of pain intensity is patients' own verbal reports (Kwekkeboom & Herr 2001). For effective assessment of pain, medical professionals must understand the biological basis, the psychosocial and environmental components in order to assess their impact on the pain experience. The barriers to effective pain management are numerous and complex. These barriers may be classified into two categories: patient and professional barriers (Carr 2007). Patient-related barriers to pain assessment include; reluctance to report pain, a fear of side effects, fatalism about the possibility of achieving pain control, and the belief that pain is indicative of a

progressive disease (Bozimowski 2012). Professional related barriers to pain assessment include; inadequate pain assessment education and a lack of systemization with in the hospitalization protocols to effectively manage pain (Carr 2007). Of significance, ICU nurses could better serve their patients by being aware of research-based pain management practices. This knowledge would allow them to become a source of accurate information for both the patients and their families, and nurses might then lead the way towards overcoming the existing barriers to providing effective pain assessment and management.

2.4.1 Patient barriers to communicating pain

Pain is a multidimensional and subjective experience (Loeser & Treede 2008), as such; the patients' self-report is the gold standard for assessment. However, many adult patients in ICUs cannot self-report pain as a result of: 1) an altered level of consciousness (Magnus & Turkington 2006), or the administration of sedative agents, 2) mechanical ventilation (Shannon & Bucknall 2013), and/or the use of neuromuscular blocking agents rendering the patient non-communicative (Carroll 2007). This results in a challenging task for the systematic assessment of pain in ICUs. ICU professionals tend to underestimate pain severity (Charlton 2005, Prkachin et al. 2007) when patients are unable to communicate verbally. Assessing pain in NVCPs is a challenge for nurses, therefore, observational pain assessment scales must be considered as an alternative.

2.4.1.1 Unconsciousness or Sedation

This seminal definition of pain indicates that pain is a subjective experience and no objective scales exist to assess it (Kamdar 2010). Whenever possible, caregivers should measure the existence and intensity of pain through patients' self-report. However, patients worldwide continue to endure pain to the extent that it may be speculated that caregivers tend to underestimate their pain (Pasero & McCaffery 2005). One reason for this may be the misguided fear of using opioid analgesics. Fear of addiction is fed by obsolete information about opioids and the unintended effects of the war on drugs (Savage et al. 2003). Many health care workers as well as patients also believe that there is a risk of addiction when employing opioids to treat pain (Gardiner et al. 2012). Information about opioids and the true nature of addiction needs to become part of the education of both patients and health professionals. This is necessary in order to remove the confusion which has made fear of addiction the number one impediment to patients reporting their pain. As a result of this fear, healthcare workers' ability to assess and manage pain effectively is negatively influenced.

Self-reporting refers to a method of obtaining information through written or oral, rather than clear articulate verbal responses. Unfortunately, some patients are completely unable to self-report their pain in any way (i.e., verbally, written, finger pointing, or eye blinks to yes/no questions) (Merkel 2002, Pasero & McCaffery 2011). Individuals who cannot communicate their pain remain a challenge and are at even greater risk of being exposed to inadequate pain management (Marmo 2013, p.45). Pasero and McCaffery (2005)

addressed five populations of patients who may have difficulty associated with self-reporting: 1) older adults with advanced dementia, 2) infants and preverbal toddlers, 3) critically ill/unconscious patients, 4) persons with intellectual disabilities, and 5) patients at the end of life. A critically ill patient may be hindered by such conditions as delirium, decreased levels of consciousness, the presence of an endotracheal tube, sedatives, and neuromuscular blocking agents. Each of these populations may also be unable to self-report pain due to cognitive, developmental, or physiological issues. These medically-induced conditions create further barriers to pain assessment and reduce the efficacy of pain management. When patients cannot self-report, the assessment and quantification of their pain becomes increasingly difficult. These difficulties are exacerbated in ICU patients, with intubation and sedative treatments often present. This prevents speech and empathic communication with the nursing staff.

2.4.1.2 Administration of treatment

In general, research suggests that the adequate use of neuromuscular blockades, analgesics, and sedatives may decrease morbidity and mortality (Walder & Tramer 2004). However, patients may be unable to communicate their experience of pain if they are already sedated, anaesthetised, quadriplegic or receiving neuromuscular blockades (Sessler et al. 2008). Pain behaviour is not necessarily clearly observable, as such; caregivers must carefully assess sedated patients. This is particularly important when high doses are being administered (Kress et al. 2000, Liu & Gropper 2003). Some sedative agents (barbiturates) neither produce muscle relaxation nor relieve pain and may,

paradoxically, heighten the intensity of the pain (Wheeler 1993). Neuromuscular blockers are useful for facilitating mechanical ventilation; unfortunately, they also obscure the diagnosis of comorbid conditions due to inhibiting patient communication. The inadvertent inhibition of normal physical responses; due to drugs that can blunt the development of fever or other phenomena, may lead to central nervous system dysfunction (Wheeler 1993). The obfuscation or masking effect induced by neuromuscular blockers may create situations in which patients are unable to communicate their experience of pain.

Most ICU patients require some form of analgesia. In 1995, the Society of Critical Care Medicine published practice parameters for intravenous analgesia and sedation in ICUs (Fullwood & Sargent 2010). Morphine (33%) and Fentanyl (33%) were the preferred analgesic agents. Midazolam (63%) or Propofol (35%) were recommended for short-term sedation, with the latter being the agent of choice for rapid awakening (Soliman et al. 2001). Propofol in combination with Fentanyl, via infusion, is commonly used for short term pain relief and sedation. However, morphine remains the most widely used for pain relief (Martin et al. 2005). Fentanyl and benzodiazepines are preferred for short sedation, while Diazepam, Lorazepam, and Midazolam are widely used for longer sedation (Ramaswamy et al. 2006). Due to unconsciousness or the administration of higher doses of sedation/analgesia pharmacological agents, pain scores may be adversely affected (Aissaoui et al. 2005, Payen et al. 2001, Young et al. 2006). This highlights the role of health professionals, especially

nurses, and emphasises the importance of these potential barriers to pain assessment.

2.4.2 Professionals' barriers to assessing pain in NVCPs

Historically, pain management has not been a priority within the health care system (Liu & Gropper 2003). To remedy this situation, the American Pain Society (Loeser 2003) suggested that clinicians routinely document a pain score as "the fifth vital sign". However, many experts have claimed that this may not actually increase the quality of pain management (Arbour & Gélinas 2010, Mularski et al. 2006). Tarigopula et al. (2014) stated that health care workers' race, age, level of education, and medical subspecialty were significant factors affecting their perceptions of pain management and intended treatment.

Pain management is a standard of nursing care endorsed by professional nursing organisations and health care regulatory agencies (Herr et al. 2006, Jacobi et al. 2002). Efficient pain management is based on accurate, thorough assessments. If the health care system fails to support innovations in pain management, the results will be both harmful to the patient and potentially increase treatment costs (Sipkoff 2003).

The choice of methods used for the systematic evaluation of pain experienced by ICU patients is predicated on the healthcare providers' knowledge. Pain, its aetiology and the healthcare providers' ability to recognize the individual's pain experience are the fulcrum of effective pain management. The ability to clearly communicate the patients' pain experience within the medical team in order to

efficiently manage pain is yet another factor (Turk & Melzack 2001). Nurses have been shown to distrust patients' self-report of pain where there is a previous history of drug misuse. A patient's ability can be also influenced by numerous factors including mood, consciousness, and medications and may result in patients not presenting pain accurately (Rose et al. 2012). Puntillo (2007) stated that the accurate assessment of pain in patients with communicative difficulties is potentially problematic. As such, nurses are forced to rely on multiple methods to determine the possible impact of medication on patients. Moreover, commonly used indicators of pain may fail to measure effectively the true extent of patients' distress.

On-going studies continue to provide more accurate pain assessment measures that benefit patients who are unable to communicate their suffering (Young et al. 2006). Gelinas et al. (2004) and Malviya et al. (2005) described the pain indicators used for pain assessment by nurses and physicians in order to verify the effectiveness of pain management in patients. They concluded that the pain documentation in medical records is often incomplete or inadequate due to the lack of both acceptance and an appropriate pain assessment tool. Malviya et al. (2005) believed that inadequate education and a lack of work-related experience may impede effective pain management. Furthermore, the reliability of the observer-based pain assessment scales depends on the quality of the training for implementing the scales (Streiner 2013, p. 276). For this reason, health care providers must be aware of the assessment procedures that are suitable for use with the critically ill patient population (i.e. unconscious and sedated patients).

2.4.3 Cultural and gender biased expressions of pain

Self-report is the most reliable measure of pain, however, patients' pain may be underestimated or overestimated due to various factors. These factors include: the nurses or patients' personalities, culture, environment and gender (Pieh et al. 2012, Tsai 2007, Turk & Okifuji 1999). Further, gender and cultural differences in terms of pain expression have been reported as major contributors to the miscommunication that frequently results in inadequate pain management (Alabas et al. 2012).

In general, women seem to be less pain tolerant than men. Previous research has demonstrated a higher prevalence of chronic pain states and greater pain sensitivity among women compared to men (Alabas et al. 2012, Wiesenfeld-Hallin 2005). A recent, large-scale survey reported that younger females were more prone to experiencing severe and enduring pain (Tocher et al. 2012). Differences in pain between the genders have been found in the pathophysiology, pathogenesis and clinical manifestations of diseases (Rokytá & Yamamotoová 2013). These differences are important with regard to assessment and treatment, which would benefit from gender-specific management. Males and females respond differently to pain and its treatment, and these differences must be taken into account during clinical pain management.

Minority patients are at high risk of suffering poor pain management outcomes. The most frequently-reported cross-cultural differences were patterns in understanding the meaning of pain and different coping mechanisms (Callister, 2003). The influence of culture on the expression of pain extends throughout

one's lifetime. The interpretation of pain and the reactions to it depend upon an individuals' life experience. This is also influenced by the behaviour of their families and other people. In traditional Asian cultures, harmonious interactions with others are very important. It is understood that individuals should never draw attention to themselves. The existence of this culture gap between patients and health care providers may increase the difficulty associated with successfully assessing and managing patients' pain (Weissman et. al. 2004). Previous research suggests that it is more challenging to assess pain in Chinese American patients. This is due to culture-related factors compounded with the patients' inaccurate knowledge of pain medication. The optimisation of pain management in this population has been found to be particularly problematic (Edrington et al. 2009, Edrington et al. 2010).

2.4.4 Current pain assessment tools

Pain is subjective, as such, an individual's self-report is the most reliable assessment (Charlton 2005, Prkachin et al. 2007). The nature of pain makes its objective measurement virtually impossible and health care professionals tend to underestimate its severity. Even if the existing multidimensional tools are reliable and valid, they may be impractical for use with special populations: 1) children, 2) people who are unable to communicate, 3) people with dementia, 4) people with post-stroke syndrome, and 5) people with mental illness (Charlton 2005). The verbal rating scale (VRS), visual analogue scale (VAS), and numeric rating scale (NRS) are reliable, valid self-rating instruments for many patient populations, but have yet to be specifically tested in ICUs (Aissaoui et al. 2005). The Wong-Baker FACES Pain Rating Scale (FPRS), VAS, and McGill Pain

Questionnaire (MPQ) are frequently used scales in clinical settings (Puntillo et al. 2009, Terai et al. 1998). However, this does not resolve the problem for NVCPs, as these tools rely on patients' ability to communicate with their care providers. Hence, behavioural-physiological parametric scales may be more useful for assessing pain in these patients (Cade 2008). Critical illness alters verbal communication with patients due to many factors: tracheal intubation, a reduced level of consciousness and the administration of sedation and analgesia. In order to provide adequate pain relief it is important to assess and document pain systematically and consistently. Currently, there is no single agreed upon pain assessment scale universally accepted for use in these patients.

A common component of behavioural pain assessment scales is the evaluation of facial expressions. Facial expressions are an important behavioural measure of pain intensity; however, inconsistencies exist with regard to defining the descriptors of facial behaviour. It is important to consider the use of alternatives for NVCPs who are experiencing pain, in order to assist in the development of concise descriptors. This may lead to an enhanced pain evaluation system and management protocol. Behavioural-physiological parametric scales may be of greater use in assessing pain in this patient group (Cade 2008).

2.5 Adult behavioural pain assessment scales

Recommendations and guidelines regarding pain management specifically in critically ill patients have been developed, especially for NVCPs (Herr et al. 2006). Despite this, pain still remains undertreated in most critically ill patients, as it is difficult to assess their pain with any precision (Gelinas et al. 2004, Puntillo et al.

2002). Accountability and responsibility with regard to effective pain assessment are essential factors for improving pain management for the critically ill. Critical care nurses acknowledge that the current pain management process, particularly the pain assessments, may not be the most appropriate. A valid method for determining and documenting pain for effective pain management in ICU patients is required. This is of particular importance for sedated, unconscious, ventilated and otherwise non-verbally communicative patients. These patients have been defined as NVCPs.

Whenever possible, health care providers must acknowledge the existence and intensity of pain through patients' self-reports. Unfortunately, some patients cannot self-report pain verbally, in writing, or by other means. These patients include; infants and preverbal toddlers, older adults with advanced dementia, critically ill/unconscious patients, persons with intellectual disabilities, and patients at the end of life. Each of these populations may be unable to self-report their pain due to cognitive, developmental, or physiological issues. Other barriers may include medically-induced conditions that make pain assessment and optimal pain management challenging. Valid assessment tools are required for effective pain assessment in these patients with communication difficulties.

It is vital to improve the assessment and management of pain in the vulnerable population of critically ill NVCPs. Currently, there is no standardised scale based on nonverbal behavioural pain indicators that may be recommended for broad utilization in clinical practice. Although several pain assessment scales demonstrate potential, these remain in the early stages of development and testing.

While the observational pain assessment scales available provide insights into the presence of pain, many questions remain unanswered. This study focuses on the most appropriate and valid assessment tools that objectively estimate the level of pain in groups of patients receiving mechanical ventilation and sedation.

2.5.1 Searching strategy

To fulfil the objectives of the study, an inventory of the existing research was necessary. Based on the objectives of the study, the search was designed to assess and select validated pain scales to further the research goal.

The MEDLINE, CINAHL, EMBASE, ScienceDirect, Academic Search Elite databases were used to identify the validated scales measuring pain intensity in critically ill NVCPs. The search keywords were adopted from the electronic MeSH databases, which is the U.S. National Library of Medicine's controlled vocabulary that is used for indexing articles for PubMed/MEDLINE. The MeSH terminology used included “pain”, “assessment OR measurement OR instruments OR scales OR behaviours OR psychometrics OR observation”, “sedation OR sedative OR unconscious OR nonverbal OR nonverbal Communication”, “intensive care OR intensive care nursing OR critical care nursing OR critically ill”, and “reliability OR validation OR validity”.

The filter function limited the articles to those published post-1990, with patients aged 19 years and older, with both an abstract and full text. The search was limited to papers published in English and Chinese. The complete filter is shown in Table 2.1 and the flowchart in Figure 2.1. Articles describing the development

or use of a validated scale for pain assessment in patients unable to communicate were included. Also articles pertaining to pain assessment using validated scales, even when not specific to the non-verbally communicative patient population. To complete our inventory of scales, the references and citations were searched.

Table 2.2 Search filter for scales for databases

AND						Limits
OR	Pain	Assessment	Validity	Sedation	Intensive	>19+ years
		Measurement	Reliability	Sedatives	Intensive care units	Abstract
		Psychometrics	Validation	Nonverbal	Intensive care nursing	English & Chinese
		Instruments		Nonverbal communication	Critical care nursing	After January 1990
		Scales		Unconsciousness	Critically ill	Medline
		Observation				CINAHL
		Behavioural				EMBASE

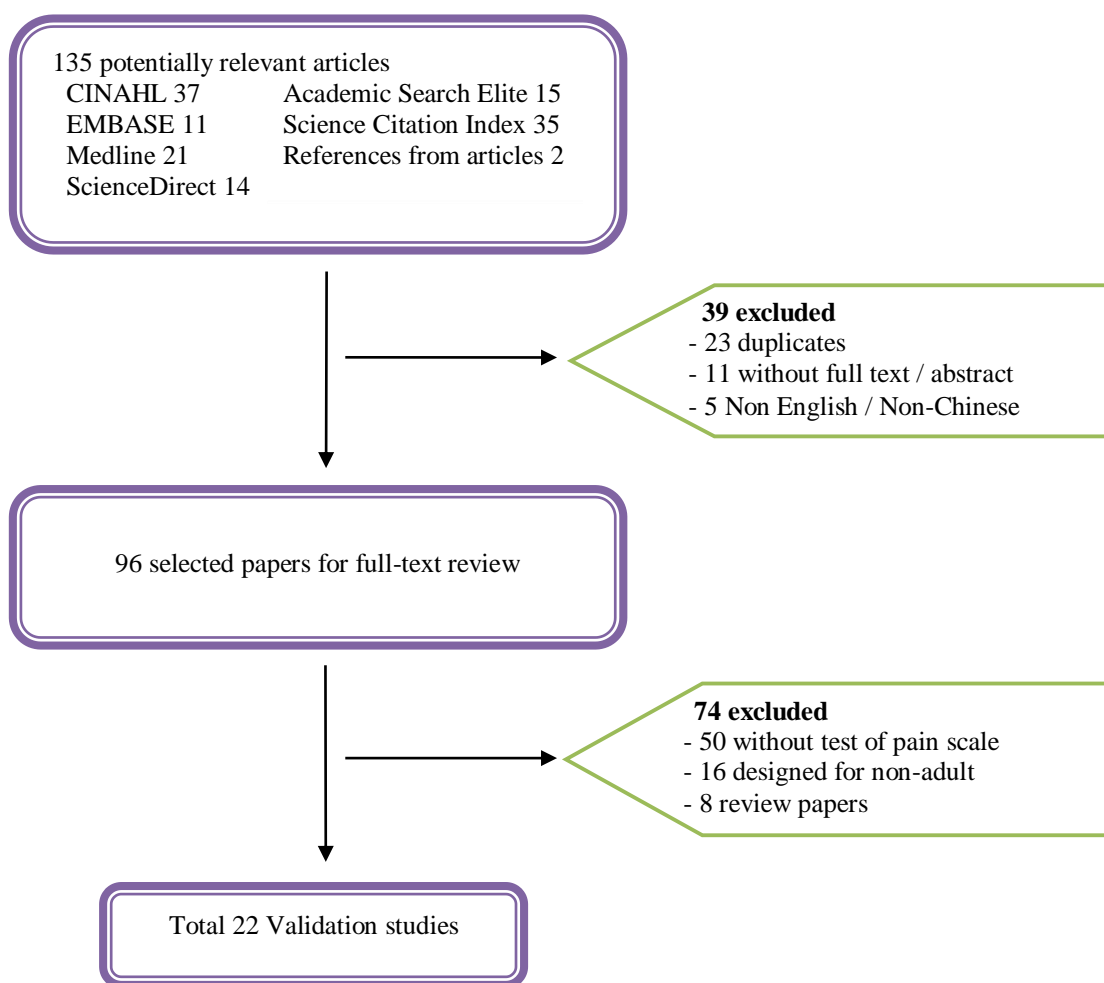


Figure 2.1 Article selection process

Abstracts were reviewed and articles were selected if they addressed objective pain observation in critically ill adult patients. Studies or reports that focused on the neonatal/paediatric population, older patients with dementia, chronic pain, palliative care, and outpatient and/or community settings were excluded. To explore additional relevant articles, this review used the “related articles option” offered by the databases to generate a cumulative list of articles. On the rare

occasion when the original article could not be found, further psychometric assessment by other authors was searched (secondary sources). When further clarification of a research article was required, the references were searched.

2.5.2 Search outcome

Unlike self-report measures, which focus on the sensory (i.e. pain intensity) and/or affective (i.e. distress) dimensions of pain; the objective measures used to evaluate NVCPs focus on behavioural and physiological parameters (Li et al. 2008). The final selection of articles for this review was based on the following four criteria: 1) research articles, 2) the availability of the full text of the article, 3) articles describing a unidimensional pain scale with multiple domains or a multidimensional pain scale, and 4) the pain scale was used with unconscious and/or sedated critical care adult patients. Additional articles were identified using the references included in these articles. The search criteria allowed for the selection of 135 papers (Figure 2.1). Based on the refined selection criteria, 22 papers regarding scales validation were relevant for the final analysis.

The 22 studies in this review comprise ten pain assessment tools: 1) Behavioural Pain Scale (BPS), 2) Critical-care Pain Observational Tool (CPOT), 3) Nonverbal Pain Scale (NVPS), 4) Face, Legs, Activity, Cry, Consolability (FLACC), 5) Nonverbal Pain Assessment Tool (NPAT), 6) Colorado Behavioural Numerical Pain Scale (CBNPS), 7) Checklist of Nonverbal Pain Indicators (CNPI), 8) Physiological Indicators (PI), 9) Numerical Rating Scale (NRS), and 10) Visual Analog Scale (VAS). The Numerical Rating Scale (NRS)

and Visual Analog Scale (VAS) were excluded, as both require the patient's verbal response. The eight pain scales that were identified for further review remain in use with unconscious or sedated ICU patients (Table 2.2). However, three of the eight pain scales were eliminated due to several factors. The CBNPS was developed for use with sedated adult patients with verbal ability as such, and was excluded from this review. The CNPI scale has not been studied within ICU settings and was consequently excluded. The FLACC scale includes behavioural indicators, crying and consolability, but no other dimensions (sensory, affective) to assess the patients' pain. FLACC is specifically designed for children and lacks ventilator compliance; therefore it was excluded from this review.

Through the selection process of elimination based on the requirements of the patient population, four pain scales remain relevant for consideration: The BPS, CPOT, NVPS and NPAT. Of crucial importance are physiological indicators (PI), which remain predictably consistent for indicating the presence of pain. The four pain scales were developed to include ventilator compliance as an indicator of pain. The CPOT and NPAT were designed for use with both verbal patients and nonverbal, mechanically-ventilated patients. By contrast, the BPS and NVPS rely solely on observable behavioural responses to pain. Although not resolved into a scale format, more consistent indicators are the PI of pain during an acute painful event. The PI data is readily accessible through the use of vital signs monitors in ICUs.

The following review focuses on quality appraisal of the pain assessment tools based on the instruments reported by Pudas-Tahka et al. (2009). The key points

of interest: 1) the origin of the items, 2) the number of participants and content validity, 3) the criterion validity, and 4) the construct validity in relation to other pain assessment tools. Of specific importance and interest with relation to the pain assessment tools, the following points were sought: 1) the number of participants, 2) homogeneity, 3) inter-rater reliability, 4) intra-rater reliability, 5) content validity, 6) criterion validity and 7) construct validity in relation to other pain tools. Table 2.3 presents a summary of the evidence on the validity and reliability of the four behavioural parametric pain scales and PI reviewed in recent studies. All pain assessment tools had been tested for both validity and reliability.

Table 2.3 Pain assessment tools for intensive care

Tools	Initial Test	Scoring method	Total scores (no pain to most pain)	Indicators						
				Facial expression	Body movement	Body tension	Ventilator compliance	Verbal response	Physiologic domain	Emotion domain
BPS	Payen et al. (2001)	Each dimension: 1 to 4	3 to 12	✓	✓		✓			
CPOT	Ge linas et al. (2006)	Each dimension: 0 to 2	0 to 8	✓	✓	✓	✓	✓		
NVPS	Odhner et al. (2003)	Each dimension: 0 to 2	0 to 10	✓	✓	✓	✓		✓	
FLACC	Merkel et al. (1997)	Each dimension: 0 to 2	0 to 8	✓	✓					✓
NPAT	Deborah et al. (2010)	Each dimension: 0 to 2 or 3	0 to 10	✓	✓	✓		✓		✓
CBNPS	Salmore (2002)	One dimension	0 to 5	Integrating with Facial expression, verbal response and body tension						
CNPI	Feldt (2000)	Each dimension: 0 to 1	0 to 6	✓	✓	✓			✓	
PI	Arbour & Ge linas (2009)	Changes from baseline		From ICU monitoring: MAP, HR, RR, SpO ₂ , and end-tidal CO ₂						

✓ *Scale with indicator*

Table 2.4 Pain assessment tools for critically ill NVCPs and a description of their reliability and validity

Tool	Studies	Internal consistency	Inter-rater reliability / Intraclass Correlation	Construct Validity	Population	Observations
BPS	Payen et al. 2001	Nil	Agreement (Tested by 2 nurses): 50% during procedure 71% at rest	Discriminant validity: scores increased from non-painful to painful situations ($p < 0.01$)	30 ICU adults	269
	Aissaoui et al. 2005	0.72*	ICC: 0.95	Discriminant validity: scores increased from non-painful to painful situations ($p < 0.001$)	38 ICU adults	360
	Young et al. 2006	0.64*	Agreement (Tested by 2 nurses): 82%~91% in 44 assessments	Discriminant validity: scores increased from non-painful to painful situations ($p < 0.003$)	44 ICU adults	176
	Ahlers et al. 2008	Nil	Agreement: 81%~100% k^{\wedge} : 0.67	Criterion validity: correlated with NRS: $r_s = 0.55$ ($p < 0.001$)	57 ICU adults	371
	Chanques et al. 2009	0.79*	Agreement (Tested by 2 raters): 90%~96% k^{\wedge} : 0.89	Discriminant validity: scores increased from non-painful to painful situations ($p < 0.001$)	30 ICU non-intubated adults	240
	Juarez et al. 2010	0.70*	ICC: 0.58 (rest)~0.68 (turn) Tested by 4 caregivers	Significant change in score from baseline compared with turn ($p = 0.000$)	200 ICU adults	968
	Chen et al. 2011b	Nil	Agreement (Tested by 2 nurses): 72.9%~100% Pearson correlations: $r = 0.50$ ~1.00 ($p < 0.001$)	Criterion validity: scores in suction was significantly higher than the score in body temperature measuring ($p < 0.05$) Discriminant validity: Scores increased during suction than other occasions ($p < 0.001$)	70 ICU patients	350

* Cronbach's α (also known as coefficient α) >0.50 moderate; >0.70 good (DeVellis 2011, Mohsen & Reg 2011)

$^{\wedge}k$ coefficient <0.40 poor agreement; 0.40 – 0.59 fair agreement; 0.60 – 0.74 good agreement; >0.80 acceptable (Viera & Garrett 2005)

Table 2.4 Pain assessment tools for critically ill NVCPs and description of their reliability and validity (continued)

Tool	Studies	Internal consistency	Inter-rater reliability / Intraclass Correlation	Construct Validity	Population	Observations
CPOT	Gélinas et al. 2006	Nil	<i>k</i> : 0.52~0.88 Tested by the investigator and the nurse	1. Criterion validity correlated with self-report pain: $\rho=0.40\sim0.59$. 2. Discriminant validity: Scores increased during turn compared with the rest ($p<0.001$).	105 CCU adults	945
	Gélinas & Johnson 2007	Nil	ICC: 0.80 ~ 0.93	1. Criterion validity correlated with self-report. 2. Discriminant validity: Scores increased during turn compared with the rest.	25 ICU adults	150
	Gélinas et al. 2009	Nil	Nil	Content validity indices >0.80	17 Clinicians	17
	Gélinas et al. 2011	Nil	Nil	Scores increased during painful procedures compared with the rest	9 ICU patients	27
	Marmo & Fowler 2010	0.89*	Agreement: 80%~ 85% Tested by 2 nurses	Nil	24 Cardiac ICU adults	58~59
	Nürnberg Damström et al. 2011	0.31~0.81*	ICC: 0.84	1. Criterion validity correlated with Vital signs: $\rho=0.32\sim0.45$ 2. Discriminant validity: Scores increased during turn compared with the rest ($p < 0.05$)	40 ICU adults	240
	Vazquez et al. 2011	Nil	Agreement: 97%~100% <i>k</i> : 0.79~1 Tested by 2 nurses	Discriminant validity: Scores increased during turn compared with the rest ($p < 0.05$)	96 ICU adults	330
	Wibbenmeyer et al. 2011	0.62~0.71	Pearson coefficient: 0.63 <i>k</i> : 0.26~0.43	1. Criterion validity correlated with self-report pain: $\rho=0.89$ 2. Discriminant validity: Scores increased during turn compared with the rest ($p < 0.001$)	38 ICU adults	225

* Cronbach's α (also known as coefficient α) >0.50 moderate; >0.70 good (DeVellis 2011, Mohsen & Reg 2011)

[^]*k* coefficient <0.40 poor agreement; $0.40\sim0.59$ fair agreement; $0.60\sim0.74$ good agreement; >0.80 acceptable (Viera & Garrett 2005)

Table 2.4 Pain assessment tools for critically ill NVCPs and description of their reliability and validity (continued)

Tool	Studies	Internal consistency	Inter-rater reliability / Intraclass Correlation	Construct Validity	Population	Observations
CPOT	Chen et al. 2011a	Nil	Nil	1. Criterion validity correlated with self-report pain: $r=0.46$ (n= 44) 2. Discriminant validity: Scores increased during suction compared with at rest ($p < 0.001$)	120 ICU patients	720
NPAT	Klein et al. 2010	0.82*	Concordance coefficient: 0.72 Weighted k : 0.35 Tested by 2 nurses	Criterion validity: Concordance coefficient with self-report of pain: 0.66	50 SICU adults	100
NVPS	Kabes et al. 2009	0.36~0.72*	Agreement: 94.7% (original NVPS); 90.8% (revised NVPS) Tested by 2 nurses	Discriminant validity: Scores decreased from painful to non-painful situations ($p < 0.001$)	64 ICU adults	121
	Marmo & Fowler 2010	0.89*	Agreement (Tested by 2 nurses): 78% for suction -79% for turning	Nil	24 Cardiac ICU adults	58~59
	Juarez et al. 2010	0.75*	ICC: 0.60~0.75 was tested by 4 caregivers	Discriminant validity: Significant change in score from baseline compared with turn ($p < 0.001$)	200 ICU adults	968
PI	Li et al. 2009	Nil	Nil	Discriminant validity: Significant changes in heart rate, pupil size, and bispectral index occurred with the noxious procedure ($P < 0.01$).	38 ICU patients	152
	Arbour & Gélinas 2010	Nil	Nil	Discriminant validity: Significant changes in vital signs during the nociceptive procedure.	105 ICU patients	315

* Cronbach's α (also known as coefficient α) >0.50 moderate; >0.70 good (DeVellis 2011, Mohsen & Reg 2011)

^k coefficient <0.40 poor agreement; 0.40–0.59 fair agreement; 0.60–0.74 good agreement; >0.80 acceptable (Viera & Garrett 2005)

2.5.2.1 The Behavioural Pain Scale (BPS)

The BPS was developed to assess pain in unconscious, mechanically ventilated patients by Payen et al. (2001) (Appendix 1). The BPS is based on the total score for three behavioural responses: 1) facial expression, 2) upper limb movement, and 3) compliance with mechanical ventilation. The BPS allows assessors to derive a score between 3 (no pain) and 12 (highest pain score). The summary in Table 2.3 shows that the BPS has moderate internal consistency, with a Cronbach α from 0.64 to 0.79, and inter-rater reliability with moderate agreement percentages (50-100%) and high inter-rater coefficients (kappa =0.67-0.89; ICC=0.58-0.95). Discriminant validation was supported with higher BPS scores during various painful procedures (suction, positioning) compared with non-painful procedures ($p < 0.001$). The BPS also had a moderate positive correlation with self-reported pain using the NRS in 13 patients (Ahlers et al. 2008).

Spanning multiple studies a total of 409 ICU intubated and non-intubated patients with postoperative pain or trauma were tested using the BPS (Ahlers et al. 2008, Aissaoui et al. 2005, Chanques et al. 2009, Juarez et al. 2010, Payen et al. 2001, Young et al. 2006). The BPS was developed and tested for its reliability and validity by Payen et al. (2001) and found to have moderate inter-rater agreement (50~71%). The study assessed change in pain scores in 30 ICU patients for painful and non-painful procedures ($p < 0.01$). Aissaoui and colleagues (2005) demonstrated that the BPS had high inter-rater reliability, satisfactory internal consistency and validity across observations of 38 ICU patients. Young et al.

(2006) examined 44 unconscious ventilated patients using the BPS during a painful stimulus (repositioning) and a non-painful stimulus (eye care), respectively. The increase in BPS score was statistically significant for repositioning ($p<0.003$) but not for eye care ($p=0.3$). Chanques et al. (2009) adapted the BPS for use in non-intubated, non-verbal ICU patients to score changes in pain. They found that the adapted BPS showed good internal consistency (Cronbach $\alpha=0.79$) and inter-rater reliability (weighted kappa coefficient=0.89) in 30 ICU non-intubated patients. The pain scores in Chanques et al.'s (2009) patients increased significantly from non-painful to painful situations ($p<0.001$). In Juarez et al. (2010) study, the BPS was shown to have moderate inter-rater reliability and discriminant validity for NVCPs in ICU ($n=200$). The use of the BPS is of growing interest in many countries due to its high reliability and validity across patient populations (Ahlers et al. 2008, Aissaoui et al. 2005, Chanques et al. 2009, Chen et al. 2011b, Juarez et al. 2010, Payen et al. 2001, Young et al. 2006)

2.5.2.2 The Critical-care Observation Tool (CPOT)

The CPOT, developed by G  linas et al. (2006) at McGill University in Quebec, Canada was originally in French and has since been translated and validated for use in English. CPOT is comprised of four different behavioural categories: 1) facial expressions, 2) body movements, 3) muscle tension, and 4) compliance with the ventilator for intubated patients or vocalisation for extubated patients with critical illness (see Appendix 2). It includes four behaviours rated on a 0-2 scale, giving a total possible score ranging from 0-8. Behaviours are rated based

on the intensity of the reaction observed, as described by the author (Gélinas 2006).

The CPOT was tested with a total of 337 ICU patients with postoperative, medical or trauma diagnosis (Gélinas et al. 2009, Gélinas et al. 2006, Gélinas & Johnston 2007, Gélinas et al. 2011, Marmo & Fowler 2010, Nürnberg Damström et al. 2011, Vazquez et al. 2011, Wibbenmeyer et al. 2011). In these studies, the CPOT demonstrated good internal consistency (standardised Cronbach $\alpha = 0.89$) and its inter-rater reliability was supported by moderate to high inter-rater coefficients (kappa = 0.52~1; ICC = 0.80~0.93) or agreement percentages (>80%) The French and English versions of the CPOT were consistent, although the Swedish version showed a low weighted kappa coefficient, suggesting problems related to translation (k = 0.26) (Nürnberg Damström et al. 2011). The discriminant validation was supported by the higher CPOT scores produced during a painful procedure (i.e. positioning) compared to rest or a non-painful procedure (i.e. non-invasive blood pressure) ($p \leq 0.001$). Criterion validation was also shown with moderate correlations between CPOT scores and patients' self-report of pain intensity at rest ($p \leq 0.001$). There is a growing interest in the use of the CPOT in countries outside Canada (Chen et al. 2011a, Kwak & Oh 2012, Marmo & Fowler 2010, Nürnberg Damström et al. 2011, Vazquez et al. 2011, Wibbenmeyer et al. 2011).

2.5.2.3 The Nonverbal Pain Assessment Tool (NPAT)

The NPAT is based on 5 behavioural components: 1) emotion, 2) movement, 3) verbal clues, 4) facial cues, and 5) position/guarding (Klein et al. 2010). Each pain behaviour is scored on a scale of 0 (“no pain”) to 2 (“extreme pain”).

The NPAT currently has one supporting study with a small sample size of 50 post-operative ICU patients, which yielded 100 observations for analysis. Painful procedures resulted in significantly higher NPAT values than non-painful procedures in concordance with self-reported pain ($r=0.66$), thus establishing the validity. Reliability was also established by a Cronbach’s $\alpha = 0.82$, but its weighted kappa coefficient was low ($k=0.35$).

2.5.2.4 The Nonverbal Adult Pain Assessment Scale (NVPS)

The NVPS involves both behavioural and physiological indicators, including the five following subscales: 1) face, 2) activity, 3) guarding, 4) physiological I (vital signs), and 5) physiological II (skin temperature, flushing, sweating and pupillary response) (Odhner et al. 2003). The physiological II category had less influence on the total score than did the other subscales (Spearman correlation from 0.219 to 0.277) (Odhner et al. 2003). Wegman (2005) revised the NVPS to include a respiratory component assessing respiratory rate, pulse oximetry, and synchrony with the ventilator. Kabes et al. (2009) compared the original NVPS to the revised NVPS and it was found to be both valid and reliable.

Observations were obtained from 348 surgical ICU adult patients in three separate studies (Juarez et al. 2010, Kabes et al. 2009, Marmo & Fowler 2010). The Juarez

et al. (2010) analysis of the NVPS on ICU patients (n=200) showed a Cronbach's $\alpha=0.75$ with ICC: 0.60-0.75 using four different raters. Kabes et al. (2009) found similarly strong results for the NVPS on NVCPs (n=64) in ICU. The revised NVPS shows good internal consistency with Cronbach's α from 0.71 to 0.89 and moderate to high inter-rater reliability (agreement: 78%~90%; ICC: 0.60~0.75) in the Kabel et al (2009) study. A significant mean increase of the revised NVPS ratings before, during, and after the pain stimulus ($p < 0.001$) further supports the validity of the scale. Marmo and Fowler (2010) used a repeated-measures study design to examine the validity of the NVPS in a sample of 25 critically ill patients after open heart surgery. They stated that the NVPS was reliable, with a Cronbach α coefficient of 0.89, but disagreement was high between nurse raters in analyses of the facial expression dimension (25% of the total observations).

Wibbenmeyer et al. (2011) did a similar study in a sample of 38 burn patients. They found that the NVPS had good internal consistency (Cronbach $\alpha = 0.80$), but interrater reliability was merely fair (Pearson correlation coefficient, 0.59). The poor reliability may have been due to the limited education of the data collectors on the appropriate administration of the tool. Discriminant validity was indicated by the change in mean NVPS scores beginning with a mean at-rest score of 0.19 and increasing to 0.44 ($P<0.001$) after the noxious stimulus was applied.

2.5.2.5 Physiological indicators

Commonly used physiological responses have not been adequately characterised in ICU patients. Findings from a paucity of studies suggest that physiologic

indicators (PI) may help detect pain in ICU patients (Arbour & Gélinas 2010, Li et al. 2009). In Li et al. (2009) study of thirty-eight ICU patients they showed significant changes in heart rate (HR), pupil size, and bispectral index during the pain inducing procedure and not with the non-painful procedure ($p < 0.01$). Arbour & Gélinas (2010) demonstrated that discriminant validity of vital signs was supported with a significant difference between baseline and during the painful procedure. However, the use of vital signs for pain assessment was not consistent in the 105 patients. Awareness of this discrepancy is important as vital signs may be evidential, when behavioural indicators are no longer available in mechanically ventilated or unconscious patients. Healthcare providers must use caution with vital signs as indicators when evaluating a patient's pain.

2.5.3 Screening instruments

BPS and CPOT are the pain assessment scales of interest in this study. The Pudas-Tahka (2009) systematic review of the current pain assessment tools scored the BPS the highest with 12 points out of a maximum of 20. The CPOT and NVPS scored lower, both with 11 points. The low scores showed that the NVPS instruments require further testing and confirmation with regard to the psychometric properties under observation. The NPAT, which was developed in 2010 requires further evaluation.

Of these five behavioural parameter assessment scales for pain intensity, only the NPAT showed moderate to strong levels of validity and reliability (Cronbach's $\alpha = 0.82$, kappa coefficient $k=0.35$). The NPAT lacks details regarding scale development and specificity for pain. This indecisive differentiation in pain scoring

is characterised by the vocalisation of pain. As such, the scoring domains remain unclear: 0-1-2 (patients can vocalise) and 0-2-3 (patients cannot vocalise).

The BPS and CPOT scales have been more comprehensively examined than the other scales, and provide good evidence of their construct validity by demonstrating patients' responsiveness to change after a noxious stimulus. The CPOT provides evidence of high criterion validity by demonstrating significant correlations between the scores measured and patients' self-reported pain intensity. In terms of reliability, the three scales (BPS, CPOT, and NVPS) reported good internal consistency within their respective subscales. However, only the BPS met the homogeneity criterion for this reliability indicator.

The NVPS showed convergent validity by demonstrating a significant correlation with nurses' pain ratings. This anomaly is of interest, as one of the behavioural items (physiologic II), which is readily observable, did not increase significantly during the painful procedure. Inter-rater reliability was also evident in the physiologic II item. Physiologic II comprises one of the five items of the NVPS, yet shows the lowest correlation with the total scale (Kabes et al. 2009). Marmo and Fowler (2010) reported that "no significant differences" were found between pairs of nurses' assessments; however, the inter-rater reliability estimates were not reported. Although Juarez et al. (2010) examined the inter-rater reliability of the NVPS, the value remains questionable. Their study failed to describe clearly what the mean score represents, as no NVPS scores were reported either at rest or during the painful procedure. Based on a careful analysis of the objective pain behavioural properties, only the BPS and CPOT provide evidence of at least three forms of validity and

inter-rater reliability. Although neither of these scales has undergone vigorous psychometric validation, they remain useful instruments. In summation and accordance with the objective of this review, only the BPS and CPOT exhibit good reliability, validity, and feasibility of use in ICUs with sedated and ventilated patients. These findings confirm the systematic review by Pudas-Tahka et al. (2009) and other similar research (Cade 2008, Herr et al. 2006, Li et al. 2008, Puntillo et al. 2009, Sessler et al. 2008).

Prior to the selection of the instruments for this study, it was essential to further test their validity, reliability and feasibility (Pudas-Tahka et al. 2009). The American Society for Pain Management Nursing supports the use of the BPS and CPOT to rate pain on ventilated patients and/or unconscious adults (Herr et al. 2006). Both pain assessment scales incorporate similar behavioural domains. Additionally, this critical review has demonstrated that the BPS and CPOT show good validity and reliability. However, they have not been tested as a pain measure for use in non-verbally communicative ICU patients in Asia.

The high inter-rater reliability and construct validity of the BPS has been demonstrated by five studies (Chen et al. 2011b, Chanques et al. 2009, Young et al. 2006, Aissaoui et al. 2005, Ahlers et al. 2005). However, when Juarez and colleagues (2010) employed four assessors to observe BPS scores in 200 ICU adults, the results showed questionable internal consistent reliability ($ICC=0.58\sim0.68$). With the BPS, there is potential for external devices to hinder patients' ability to exhibit upper limb movement, one of the behaviours on the scale. Furthermore, the BPS descriptors of ventilator compliance are not clear parameters, which may affect

the reliability of the observer response. By contrast, the validity and reliability of the CPOT was established with moderate to good statistical values by four separate studies (Gélinas et al. 2006, Gélinas & Johnston 2007, Marmo & Fowler 2010, Nürnberg Damström et al. 2011). The CPOT scores for the painful procedure were significantly higher than those for the non-painful procedure, with $p < 0.005$ (Chen et al. 2011a, Gélinas et al. 2006, Gélinas & Johnston 2007, Nürnberg Damström et al. 2011, Vazquez et al. 2011, Wibbenmeyer et al. 2011). Interestingly, Wibbenmeyer et al. (2011) in their study on 38 burn patients found the patients were able to self-report and supports the criterion validity with $\rho = 0.89$. However, inter-rater reliability of the CPOT showed fair agreement with the weighted kappa of $k = 0.26 \sim 0.43$, even though the Pearson coefficient indicates a moderate positive linear relationship, with 0.63 suggesting the CPOT domain items are in correlation with the objective observer.

The inter-rater reliability differences for both the CPOT and BPS across these studies may be related to the training of the observers. Unfortunately, descriptions of the training procedures were not provided by many studies. The CPOT contains operationally defined descriptors and a clear scoring system not dissimilar to the BPS. In addition, it was designed for use with both verbal and nonverbal, mechanically ventilated patients. An important observation within the concurrent criterion validity was demonstrated by the high CPOT scores for patients who self-reported pain and supported by the same patients with low CPOT scores who self-reported the absence of pain (Chen et al. 2011a, Gélinas et al. 2006, Gélinas & Johnston 2007, Wibbenmeyer et al. 2011). This suggests that the CPOT may be an overly sensitive objective instrument in some cases.

The findings from studies of objective pain measures provide useful information to direct the development and support the use of the CPOT and BPS in heterogeneous, critically ill NVCPs. While the validity and reliability of these behavioural pain scales have been accepted in western countries, they have yet to be thoroughly examined for use in Asia and elsewhere. Kwak and Oh (2012) demonstrated that the CPOT scores in a sample of 202 critically ill Korean patients during suctioning differed significantly from those while at rest ($p<0.001$). The inter-rater reliability was found to be acceptable, with weighted kappa coefficients of 0.81-0.88. Unfortunately, the details of this study cannot be reviewed, as this article is currently only available in Korean. By contrast, the work of Chen et al. (2011a), which focused on the use of the CPOT in the Taiwanese population, failed to measure inter-rater reliability. At present, there remains a void in the research available to assess the usefulness of CPOT with Asian populations.

Pain scales require careful translation from the original language into the language of the nation where it will be utilized. Chen (2011b) translated the BPS into a traditional Chinese version in order to study its use with Taiwanese populations. In this study, a significantly higher score during painful procedures compared with non-painful procedures was evidenced ($p<0.001$). They also reported high agreement between two nurses (72.9%~100%), whereas the test-retest reliability with the Pearson correlation coefficient was rated about $r = 0.50\sim 1.00$ ($p<0.001$). Chen's (2011b) study, a single group design, was conducted in an ICU with 72 participants. As such, these results lack the characteristics of generalisation or randomisation (Smith 2008). Additionally, because pain fluctuates over time, a high

index of test-retest reliability is not the goal, as this may indicate insensitivity to change rather than reliability across time (Turk & Melzack 2001).

To maximise the preliminary evaluations which have established the effectiveness of these tools (BPS and CPOT), the validation of multiple language versions is necessary. Further research to examine their feasibility and utility in a heterogeneous population of NVCPs and experiencing pain is needed.

2.5.4 Current tools in clinical use

Medical research seeks innovative strategies to increase knowledge and improve current clinical practice. Currently, Taiwan ICUs rely on the Wong-Baker FACES Pain Rating Scale (FPRS) (Appendix 3). The use of FACES presents a conundrum to the current research as the literature review strategy was limited to adult patients. The FPRS was designed and is used in western countries in the field of paediatrics. It is the currently preferred and validated scale for pain assessment in adult Chinese NVCPs (Li et al. 2007). FPRS is a tool that is employed worldwide for paediatric pain assessment, with standardisation in Chinese, French, Japanese, Italian, Korean, Portuguese, Romanian, Spanish, and Vietnamese (Chambers & Craig 1998, Paik & Ahn 2002). As a subjective quantitative tool, the FPRS consists of six cartoon-type faces, scored from a smiling “no pain” face (scored as 0) to a crying “most pain” face (scored as 10).

According to a systemic review, FPRS with smiling no-pain anchors may provide greater pain scores in comparison with other scales (Tomlinson et al. 2010). Studies by Chambers et al. (2005) and Hunter et al. (2000) compared several other face

scales alongside other self-report measures (i.e. numbered scales of pain) and demonstrated high correlations (greater than $r>0.8$) for scores using multiple self-report scales. Regardless of the high correlation between these scales, the FPRS fails to provide information about the accuracy of the agreement between the scales with respect to the patient's real perception of pain. Moreover, it was designed for use with children aged three years old and upwards, and remains useful in the assessment of cognitively impaired patients (Hunsley & Mash 2008). It offers a visual depiction for those lacking the verbal ability to describe their discomfort. However, the FPRS provides a description indicating what kind of pain goes with each facial expression. This inadvertently encourages the caregiver to make subjective judgments regarding patients' levels of pain. A previous study reported the existence of poor agreement between the parent, practitioner, and child self-reported FPRS pain scores (Singer et al. 2002). Most studies have also shown that parents (and nurses) underestimate children's pain (Chambers et al. 2005). The primary concern with the FPRS is the confounding of emotion with pain intensity in the representation of the faces.

The FPRS has adequate psychometric properties, is easy to use and inexpensive to reproduce (Stinson et al. 2006). The greatest strength of this scale is its acceptability, given the consistent findings that the FPRS is preferred by children, parents, and nurses when compared to other pain scales (Chambers et al. 2005, Luffy & Grove 2003). However, Lewis (2007) suggests that the FPRS may convey different meanings for those who use different types of sign language. Some symbols similar to the FPRS are commonly used to convey emotions such as humour and teasing in

the deaf community. The suitability and reliability of the FPRS remains dependent on its acceptance by both patients and health care staff.

2.6 Approaches to reliability and validity

Scale reliability and validity are among the assumptions that justify the substantive inferences made based on the analysis of a data set. As such, they can be considered as auxiliary hypotheses that are amenable to testing (Bannigan & Watson 2009). Reliability is specific to the scale in the population represented by the study sample (Streiner & Norman 2008). Based on this premise, the pain scales adopted for use in this study were further evaluated for reliability and validity using a pilot study prior to initiating part 2, the larger study sample.

What are the factors that determine the pain assessment scale that the nurses will use? In an increasingly evidence-based practice environment, it is vital that the instruments used are reliable, valid, and practical (Downing 2003). As will be covered in Chapter 3, to establish the reliability, validity and utility of the study instruments, this study used both the qualitative and the quantitative approach. In qualitative research, the need for validity, reliability, and generalisability has been the subject of debate. This focus is on their appropriateness in the qualitative as opposed to the quantitative paradigm. In Kvale's (1995) seminal work, it was stated that validity, reliability, and generalisability have "attained the status of a scientific holy trinity" (p.20). Yardley (2008) further explains why these terms are inappropriate for qualitative research. Quantitative research relies upon the elimination of error caused by the influence of the researcher, whereas qualitative research accounts for it. Moreover, quantitative research aims for reliability and the ability to apply observations to the entire

population. Qualitative research, in contrast, investigates and values the effects of context and individual differences (Yardley 2008). However, recent literature from England has highlighted that many studies utilising instruments to measure the patient experience have provided limited information on their reliability and validity (Evidence scan 2013). Tobin and Begley (2004) stated that, if validity and reliability are rejected, then the basic concept of rigour is also rejected. Therefore, to comprehensively evaluate these three scales fully, they must, as a minimum, meet both the required reliability and validity standards in part 2 of the research. The details of the in-depth examination to establish reliability and validity will be presented in the background sections of Chapters 4 and 5. In addition, from the perspective of clinical practice, Chapter 6 will present the qualitative approach to assess the practicality of employing these three pain assessment scales on the ward.

2.7 Summary

Pain is an undeniable problem in the healthcare world today. Pain assessment in ICUs remains a serious challenge for both clinicians and health care researchers. There is no specific neurobiological parameter or tool for the evaluation of pain, nor does an objective quantification of pain intensity exist (Dimopoulou 2005). This literature review has demonstrated specific issues which need to be considered when assessing pain in NVCPs. A number of scales have been identified that can be used to assess the impact of interventions aimed at improving pain management in patients who are critically ill. However, the current literature lacks sufficient evidence of a clear and reliable method to assess pain in unconscious and/or intubated patients, who cannot verbally communicate with their healthcare providers.

Research reports need to contain clearer definitions of the concepts used to describe the communication ability of the patient population studied and their awareness of their pain, in order to avoid confusion in this regard. In addition, the selection of the BPS, CPOT, and NVPS is based on their exhibition of consistent reliability and validity. The BPS has been compared in its validation criteria with the NRS, VAS (Ahlers et al. 2008), and NVPS (Juarez et al. 2010). Similarly, the validation criteria of the CPOT have been compared with those of the NVPS, FLACC, NRS, VAS, and physiological indicators (Mermo & Fowler 2010, Wibbenmeyer et al. 2011, Gélinas & Arbour 2009). Currently, no studies have evaluated both the BPS and CPOT for assessing acute pain in Chinese patients with critical illness. It is of particular interest to determine whether the BPS or CPOT is best suited for patients who cannot communicate. At present, the FPRS remains the preferred, validated scale for pain assessment in Chinese adults (Li et al. 2007, Li et al. 2009). To ensure optimal use in clinical settings, these pain assessment tools (the BPS, CPOT, and FPRS) require further psychometric testing with Chinese adults in ICU settings. The results may then be used in Asia to implement a systematic comparison of multiple pain scales in ICU patients with mechanical ventilation and sedation.

The available research at present does not address several parameters of importance to the current focus. As such, the implementation of an empirical study, its design, how it will be conducted and reported will be addressed in Chapter 3.

CHAPTER 3: Methods

3.1 Introduction

The previous chapter outlined the current knowledge in the field of behavioural observational pain scales as an element of pain assessment in ICUs. The specific characteristics of the tools for assessing pain in ICU patients without the ability to communicate verbally were examined. The research question was derived from this review of the literature and is restated here:

Are the Behavioural Pain Scale (BPS), Critical-care Observational Tools (COPT), and Face Pain Rating Scale (FPRS) practicable pain assessment tools for use by Chinese nurses with patients with communication difficulties?

This chapter addresses the investigative approaches utilized based on the qualitative and quantitative nuances of the research question. This then will lead to a comprehensive understanding of how practicable these pain scales are when in use. Clarifying the term ‘practicable’ with respect to pain scales will allow the research to proceed to quantify the defined variables. The research has been arranged in three logical phases. The first phase aims to define how practicable the three pain scales are, in terms of content construct and cultural adaptation, as a desirable outcome of translation. The second phase is required to quantify the validity and reliability of the outcome of phase 1. Finally, phase 3 aims to establish the possible relationship between the outcome of phase 2 and the implementation of the three pain scales in clinical practice. This three phase method is known as embedded mixed methods research.

This chapter explains the role of validation and utility in these pain assessment tools. The compatibility of sequential mixed methods, scales evaluation and exploratory research is discussed. As the research is divided into two phases, this chapter will focus on the holistic principles of the methodology adopted. The research design implemented for each research phase will be discussed in Chapters 4 to 6.

3.2 Research questions

Based on the literature review of multiple observations based behavioural pain assessment tools, the BPS and CPOT instruments have been identified as potentially appropriate scales for pain assessment of NVCPs in ICU settings. These instruments have been found to be superior to other scales for reliably detecting pain (Herr et al. 2006, Pudas-Tahka et al. 2009, Sessler et al. 2008). At present, the FPRS is used to score pain in sedated and ventilated patients; however, it may not be the most appropriate scale for this patient population. The goal of this study is to generate a Chinese version of these two scales and test their psychometric properties. Additionally, the study identifies and compares the practicability of the scales based on the responses of nursing staff in the critical care field.

The primary research objectives of the present study are as follows:

1. The objective of the intervention study is to translate the BPS and CPOT into the Chinese version. Further to which the translated versions of the CPOT and BPS as well as the FPRS will be validated for pain assessment by Chinese-speaking nurses with ICU NVCPs.
2. The descriptive study is to explore the attitudes and perceptions with respect to pain. Pain assessment and the experience of nurses working with the BPS, CPOT,

and FPRS in ICU settings are also explored.

Subsidiary research questions provide the basis for exploring the concept of “practical pain assessment tools”. Tool practicability depends on the desirable outcome(s) of scales’ development and their validation in clinical ICUs.

- RQ1. Can the BPS, CPOT, and FPRS be used to rate pain intensity in NVCPs?
- RQ2. What are the reliability and validity of the BPS, CPOT, and FPRS when used to rate pain from non-painful to painful stimulus in NVCPs with critical illness?
- RQ3. Which of the BPS, CPOT, and FPRS is the most responsive measure?
- RQ4. What are the similarities between the BPS, CPOT, and FPRS when used to quantify pain?
- RQ5. What is the preferred scale of nurses when assessing NVCPs’ pain in clinical practice in ICU settings?

This research proposes five research questions which have been designed to direct the research and provide a comprehensive answer to the main research question. To ensure that the scales are appropriate for assessing pain in NVCPs, this research explores how the three pain instruments function in the ICU setting. The latter aim of the interpretive study is to explore in greater depth the receptivity to these pain assessment tools. The influence of personal, social and contextual factors on the quantitative measures is examined.

3.3 Research design

The combination of deductive and inductive approaches shapes the way in which researchers gather information, perceive the world, and search for evidence to support their beliefs (Parahoo 2006). Quantitative research tends to emphasise deductive reasoning, the rules of logic, and the assessable attributes of the human experience

(Knapp 1998). Thus, quantitative research has its roots in logical positivism (Bryman 2008a). Qualitative research is often considered “soft” because it does not deal with precise numbers nor have the apparent “objective reality” that is characteristic of the quantitative approach (Parahoo 2006). To emphasise the dynamic, holistic, and individual aspects of the human experience, it is essential to select complementary approaches that balance their respective strengths and weaknesses (Johnson & Onwuegbuzie 2004). This study illustrates the use of these pain measurement scales and their impact in providing a holistic evaluation of pain management. Mixed methods research will advance the knowledge of these three pain assessment scales as they are utilised within the ICU setting.

A mixed methods design was selected in order to comprehensively answer the research questions. The embedded mixed methods design includes qualitative data in order to enhance and quantify patients’ subjective experience of pain and the responsiveness of the assessment tools. This distinguishes the embedded design from a convergent design, where the research employs both quantitative and qualitative approaches to address the main research question. This section explores the five research questions and the evaluation method of the three pain scales in use with NVCPs. The process of designing a research methodology is unique to the problem being investigated (Trochim 2006). According to Trochim (2006), a good research design includes five criteria: 1) theory-grounded, 2) situational, 3) feasible, 4) redundant, and 5) efficient. Accounting for the preceding criteria, a good research design will promote a unique framework for each research question (Trochim, 2006). Research in the field of construction management acknowledges the same principles. Kumaraswamy et al (1997) noted that a methodology is influenced by: 1) the contours of the data domain,

2) capacity, 3) the limitations and resources of the researcher, and 4) the envisaged outputs and presentation format. The construction and implementation of a research study that can produce applicable and useful knowledge is rooted in the quest for deeper understanding. For the research to intrinsically be of value it must in some manner illuminate the focus of interest or lead to refinement of the research method regarding the point of interest.

Subjective data, if measured repeatedly, will produce different outcomes. It is unlikely but possible that one evaluation method will be identical to another. The data collected as part of the evaluation process may be affected in part due to the method of collection and the data type sought. Some data will be numerical, such as frequencies or summative and formative assessment results, while other data may be textual, verbal, graphic or observed. The embedded mixed methods design allows the analysis of both quantitative and qualitative data and their mutual influence on each other. Holliday (2007) recommends recognising the distinctions in analysis between qualitative and quantitative data with caution, as “Qualitative research will always involve quantitative elements and vice versa” (p.2). Quantitative data lends itself to statistical analysis which, when handled correctly, can produce results which are valid and reliable. Statistical significance can be used to predict with a set degree of confidence that a similar result may be achieved in future research. Fundamentally, it suggests that this result has not been obtained simply by chance. At the beginning of the 21st century, effect size was introduced in the field of psychology (Kelley & Preacher, 2012). This established where a relationship exists and the strength of the influence of one variable over another. Where samples are particularly large, quantitative data facilitates more rapid analysis than qualitative data. While quantitative analysis may be conducted and

results produced within a relatively short time, any confounding variables revealed are limited to the point in time when the data was collected.

Statistical analysis allows for two strategies: descriptive and deductive results (Antonius 2013, p.9). Typically, descriptive analysis is a useful precursor to other analyses in order to illustrate the characteristics of the sample. Deductive analysis predicts what may happen in the future, by showing where relationships and patterns exist. In this respect, the collection of quantitative data “helps in making judgements when there is insufficient information to be certain of what will happen” (Bryars, 1983, p. intro). Care must be taken to avoid attributing causes to statistically significant results. A relationship may exist, but the direction of influence between the variables must be tested, not merely assumed.

Qualitative research uses a number of strategies of enquiry, i.e. ethnography, grounded theory and action research. These strategies are not mutually exclusive (Holliday 2007). Holliday (2007) states that each strategy can use different methods of data collection and analysis. These may include: interviewing, observation and content analysis. Mayring (2000) describes combining qualitative content analysis with other qualitative techniques. Hsieh and Shannon (2005) describe grounded theory as an analytical approach which goes “beyond content analysis to develop theory” (p.1281). It is a reasonable conclusion that a strategy could indeed go beyond the basic analysis to design a theory. As such, grounded theory indeed constitutes a deeper analytical process than simple content analysis.

Content analysis assumes that people have beliefs or opinions about an experience or topic that can be reliably inferred from an analysis of their statements (Wilkinson

2008). Therefore, one aim of content analysis is to identify the participants' beliefs. Content analysis involves systematically categorising statements of belief or opinion into collective, coherent themes. Hsieh and Shannon noted that, for a time, it was fashionable in research to reduce text to codes, categories and frequencies that could then be statistically analysed (Hsieh & Shannon 2005). Categories were extracted from the data (as in grounded theory) or the researcher's pre-conceived ideas (known as the top-down approach) (Wilkinson 2008). However, this study will focus on thematically analysing qualitative data in relation to the primary research question, in order to explore the latent content from the focus group interview.

There are several disadvantages to thematic analysis, primarily the loss of detail. This is due to reticence on the participants' part and coding problems that occur when collating many quotes into themes (Guest 2012). To reduce the potential for error due to coding problems, the line of questioning via interview can be made more succinct.

Based on the advantages and disadvantages of the qualitative and quantitative approaches, the mixed methods embedded design was selected. It was deemed the most appropriate for exploring the primary research question. This interpretive study draws on combined research methods to examine and compare the BPS, CPOT, and FPRS from multiple perspectives. As mentioned in Section 3.4, the embedded mixed methods design is employed to address the qualitative aspect of the research and quantify the primary research question. The five research questions reflect the three phases of the study: 1) a translation of the existing pain assessment scales was undertaken to establish the content and context of the items; 2) a prospective evaluation study was conducted to examine the pain scales for further validation; 3) a

focus group interview was then conducted to explore the feasibility and utility of these scales. The next section will discuss the procedures related to the embedded design in order to focus on data related to the primary research question. The reasoning for the inclusion of the qualitative aspect of the research will be addressed.

3.4 Embedded mixed methods framework

In this embedded experimental design, the study begins by conducting tests to examine the three scales using a quantitative experimental design. This involves targeting NVCPs with various conditions. The second phase of the study is qualitative and designed such that it builds on the results of the first, quantitative phase. Focus Groups (FGs) were then utilised to interpret how the qualitative results explain the initial quantitative results (Figure 3.1).

This aspect of the research was conducted in three stages, from January 2011 to September 2012. The first and second stages consisted of the translation and validation of the BPS, CPOT, and FPRS. Phase 3 was designed to enhance understanding of the feasibility of assessing pain in NVCPs from the nurses' perspective.

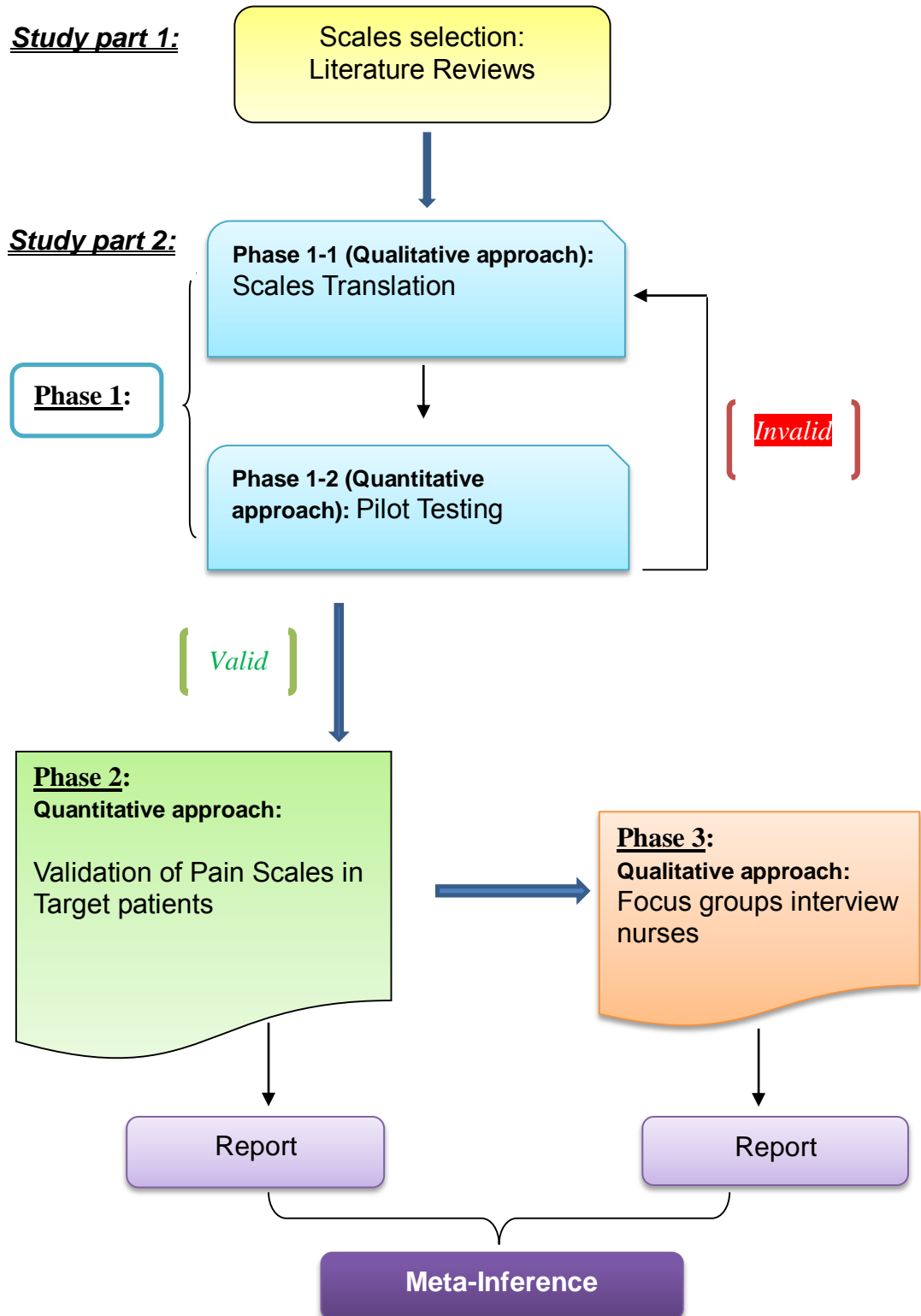


Figure 3.1 Mixed methods research processes adopted from Creswell & Plano Clark, 2007

In section 3.2, RQ1 provides the context for the pain scales of the research. The findings relating to RQ1 will facilitate the preliminary validation of the pain scales. The research will seek to assess whether or not the three pain scales are suitable for indicating pain during the pain-inducing medical interventions or pain endemic to the patient. RQ2 aims to confirm the data provided by the patients' pain scores by using the pain scales during non-painful or painful procedures. Addressing RQ3 has important implications for investigators who wish to select the most appropriate pain scale for use. The RQ4 queries the similarities in the pain scales of interest. RQ5 builds on the responses to RQ4 by asking if the outcomes identified in RQ3 have been achieved. Logically, RQ2 and RQ3 must be answered before RQ4 can be investigated. The scales evaluation requires an appropriate comparison process to be identified. The answer to RQ5 will then build on the outcome of RQ4. The literature presents evidence of a strong relationship between scales evaluation and the embedded mixed methods framework. However, it cannot be assumed that the embedded mixed methods as discussed are the most appropriate for the current research. The evaluation process to examine both the scales and the research questions can be found in Table 3.1.

It further maps the questions and scales evaluation process to the proposed embedded mixed methods phases. Table 3.1 illustrates the integration of the two research phases: phase 1 is the methodology employed to translate and validate the pain scales. Phase 2 addresses the questions RQ2 and RQ3 which prepares the basis for phase 3. Phase 3 uses a qualitative methodology to establish the feasibility and utility for assessing pain in NVCPs using the pain scales of interest. A key outcome of this phase will be the

feasibility and utility in terms of the dependent variables and the selection of an appropriate tool for quantifying these variables. As more than one dependent variable is possible, the research will remain open during the exploratory phase of the process. As phase 2 and phase 3 of the study is run concurrently, the research hypotheses can be constructed at the conclusion of phase 2.

Table 3.1 Mapping of the methodology, the research questions and the phases of the sequential mixed methods framework.

Research questions	Study stages	Research method adopted
RQ1. Can the BPS, CPOT, and FPRS be used to rate pain intensity in NVCPs?	Phase 1	Literature review to determine pain assessment instruments. Interview experts to obtain content validity on pain scales and pilot test these to confirm accurate scale translation.
RQ2. What are the reliability and validity of the BPS, CPOT, and FPRS when used to rate pain from non-painful to painful stimulus in NVCPs with critical illness?	Phase 1 & 2	A prospective evaluation study to measure performance criteria and quantitative data on activities implemented and intended outcomes.
RQ3. Which of the BPS, CPOT, and FPRS is the most responsive of the measures?	Phase 2	A prospective evaluation study to determine the performance indicator instrument.
RQ4. What are the similarities between the BPS, CPOT, and FPRS when used to quantify pain?	Phase 3	Interview scale users to confirm that pain scales implemented and measure the performance criteria.
RQ5. What is the preferred scale of nurses when assessing NVCPs' pain in clinical practice in ICU settings?		

Oliver (2004) supports the use of multiple phases in an exploratory research project as a method for developing a theory which is grounded in the data. An initial problem serves to stimulate research from which a theme is identified, and the secondary finding of the theme itself is deemed worthy of further investigation. The following section provides a general discussion of the ethics component with regards to the study.

3.5 Ethical considerations

Six ethical principles exist related to conducting nursing research which researchers use to protect their patients/subjects from harm (ICN 1996). These principles are: 1) beneficence, 2) non-maleficence, 3) fidelity, 4) justice, 5) veracity, and 6) confidentiality. These have been synthesised into four rights to which research participants are entitled: 1) the right not to be harmed, 2) the right to full disclosure, 3) the right to self-determination, and 4) privacy, anonymity and confidentiality (ICN 1996).

To implement the participants' right not to be harmed, this survey was self-audited by the primary researcher. The ethical standard is the checklist of the Level 1 Ethics Review of the School of Health in Social Science Research Ethics Committee at the University of Edinburgh. Where the checklist confirmed any potential for significant risk, or required ethical review, the level 2 procedures were followed. The subject area research ethics team at the University of Edinburgh approved this study on March 31, 2011 (Appendix 4). After receiving University Institutional Review Board (IRB) approval in Scotland, IRB approval in Taiwan was sought. This empirical study was submitted to the Taiwan IRB branches of each clinical practice to confirm the absence

of any reasonably foreseeable ethical risk. The process of obtaining Hospital IRB approval required an additional two months. Four regional Research Ethic Committees approved the study. The following codes are the approval numbers obtained from each research ethic committee: Taipei: 201104007 (Appendix 5), Hualien: IRB100-23 (Appendix 6), Taichung: 00-IRB-006-M (Appendix 7), and Chiayi: B10002014 (Appendix 8).

In order to protect patients' rights and ensure non-interference with their ongoing medical treatment, the actions of the investigator must be clearly delineated. Phases 1 and 2 of this research progressed as a quantitative evaluation study in an active clinical setting. The results were recorded on a data collection form and included BPS scores, CPOT scores, FPRS scores, and medical records. Therefore, in this study, the investigators could only observe and collect qualitative and quantitative data regarding the health and pain levels of NVCPs. In doing so, they cannot and do not affect or alter any care or services offered by the nurse. In this manner, any potential for conflict between the investigator and the clinician is minimised. Detailed descriptions of the study procedures will explain the methods employed to minimise the risk of harm to the participants throughout this study.

Research involving unconscious participants differs from standard research as the participants are unable to provide informed consent at the time of the data collection. To ensure full disclosure, informed consent was obtained from surgical ICU patients on the day of their surgery or the day before. In patients where a dramatic loss of consciousness was present, consent was requested from their legal guardian. Due to the nature of this study, informed consent was necessary from both the patients and

the nurses on the ward. After obtaining Research Ethics Committee approval, a clear cover letter and individual explanation of the study was drafted. Each of the prospective patients (or their next of kin) and nurses were recruited. With a full understanding of the study procedures, together with the potential risks and benefits, the participants granted permission for their data to be collected. In this interpretive study, the data collection process involves two approaches. The quantitative research aspect of this study required individuals to provide their informed consent (Appendix 9) to participate and have their behaviour observed. In the qualitative research component, the researcher guarantees anonymity and the right to withdraw from the study at any point. This is stated on the consent form and the participants' signatures are required (Appendix 10).

Protecting the anonymity and confidentiality of research participants' information is another practical component of research ethics. Anonymity is preserved by: (1) aggregating data in tables and (2) setting rules that ensure that a minimum number of units is available before the data/information can be presented. At no point is raw data made accessible to any parties who are not directly associated with the data collection and analysis.

3.6 Summary

This chapter reviews the appropriate use of quantitative and qualitative data. A sequential exploratory mixed methods approach to the research is adopted. This method is particularly useful for research that has the goal of programme evaluation (i.e. pain assessment) as a primary motivation. Within this methodology, the pragmatic paradigm is adopted, as this best suits the requirements of the research to remain

flexible. This is due to the sources and types of data collected. Quantitative data was collected in the scales development and pilot test components. Due to the dual nature of the data, both quantitative and subjective recollections of events in qualitative form were required. The data interpretation, while accounting for potential, researcher influence and bias without promoting it, was implicit. In this manner, the research was able to design and refine methods that are better suited to the research question under investigation. This flexibility is superior to a poorly-fitting method that fails to account for cultural and study context factors. Characteristics specific to the method adopted for this research include the division of the research into two main stages. The first, consisting of two phases (phases 1 and 2), is the scales development and quantitative validation. This is followed by phase 3, an exhaustive analysis of the qualitative data.

The translation of the study instruments for use in the first phase of this study and their validation is necessary prior to engaging in phase 2. The next chapter (Chapter 4) will describe in detail the method specific to phase 1. The steps associated with the difficulties in conducting language translation and the pilot testing of the pain scales will be discussed.

Chapter 4: Phase 1: Pain scales' development

4.1 Introduction

The research evaluates the practicability of Behavioural Pain Scale (BPS) and Critical-care Pain Observational Tools (CPOT). These scales have been evaluated in western populations, with one small study based in Korea (CPOT) and another in Taiwan (BPS, CPOT). Due to the small population size involved in these studies, generalization is not possible. The remainder of this chapter details the research process which constitutes phase 1. This entails the translation of the BPS and CPOT for use in pain assessment in Chinese speaking Taiwan.

4.2 Translation and adoption in a cross-cultural context

The BPS and CPOT were not developed well in the Chinese language and have not been widely tested for robustness with Chinese populations (Pudas-Tahka et al. 2009). To test the BPS and CPOT on the proposed subjects, a validated Chinese version must first be developed.

Translation is the most common method for altering assessment scales for cross-cultural research. However, problems exist that may potentially threaten the research validity, and so must be overcome (van de Vijver & Tanzer 2004). The specific validation method adopted is less important than the recognition that the translation process must be appropriate and the validation process rigorous (van de Vijver & Tanzer 2004). Although team translation procedures have been recommended (Harkness 2003), established gold standards for good instrument translation and interpretation do not exist. Consequently, this study employs two accepted methods of

translation. The questionnaire translation procedure, based on Harkness' (2003) recommendations, was incorporated into the process. The seminal translation work of Brislin (1986) on computer translating programmes was also employed to alter these scales.

Translations are to involve a minimum of two independent forward translations, using bilingual translators. These versions are then compared to identify discrepancies that are indicative of ambiguous wording within the original survey or other problems (Harkness 2003). Back translation can improve the reliability and validity of research in different languages. This is accomplished by requiring that the quality of a translation be verified by an independent translator translating it back into its original language (Harkness 2003). When a new or pre-existing scale is developed or altered, it is necessary to provide extensive information about its reliability and validity.

Scale developers need to employ appropriate processes for item selection and review. As part of the scale assembly, researchers must ensure that potentially offensive (or biased) content or language is avoided and that the scale content is relevant for its intended use. Evidence suggests that differences in performance across major subgroups are related to the construct being measured. Performance differences are not due to construct irrelevant variance and remain the responsibility of the developers to account for (Joint Committee on Testing Practices 2004). Following rigorous scale development procedures, the content validity of the construct to be measured must be assessed in order to draw conclusions about the scale's accuracy (Polit & Beck 2004). In order to ascertain the content validity, the guidance of specialists, experts' reviews and adjustments may be required (Polit et al. 2007). Assessing the design and practicability of a scale requires a pilot study to be conducted (van Teijlingen et al.

2001). Conducting a pilot test of the pain scales of study interest will provide useful preliminary evidence. This will briefly assess the potential for feasibility, clinical efficacy data and provide valuable insights for the main study (Friedman 2013, Thabane et al. 2010). Based on the accepted translation methods, the pre-final versions of the BPS and CPOT will be used in a pilot test for a preliminary assessment of reliability and repeatability.

4.3 Aims

The purpose is to evaluate a translation of the BPS and CPOT in the Traditional Chinese language that is spoken in Taiwan. The translation accuracy, content validity and health caregivers' clear understanding of how to use the scale to assess pain in NVCPs is investigated.

4.3 Methods

This study is characterized as methodological in nature. As the pain scales employed in this study were translated from their English versions, permission was sought from the original authors. It is unnecessary to obtain permission to reproduce a copyrighted work in order to develop scales for non-profit academic research (MacQueen 2010). According to Harkness (2003), Streiner and Norman (2008), a concise guide to adapting measures for cross-cultural use involves a four-stage process of translation: 1) forward translation, 2) back translation, 3) expert reviews, and 4) adjustments and a pilot study (Figure 4.1).

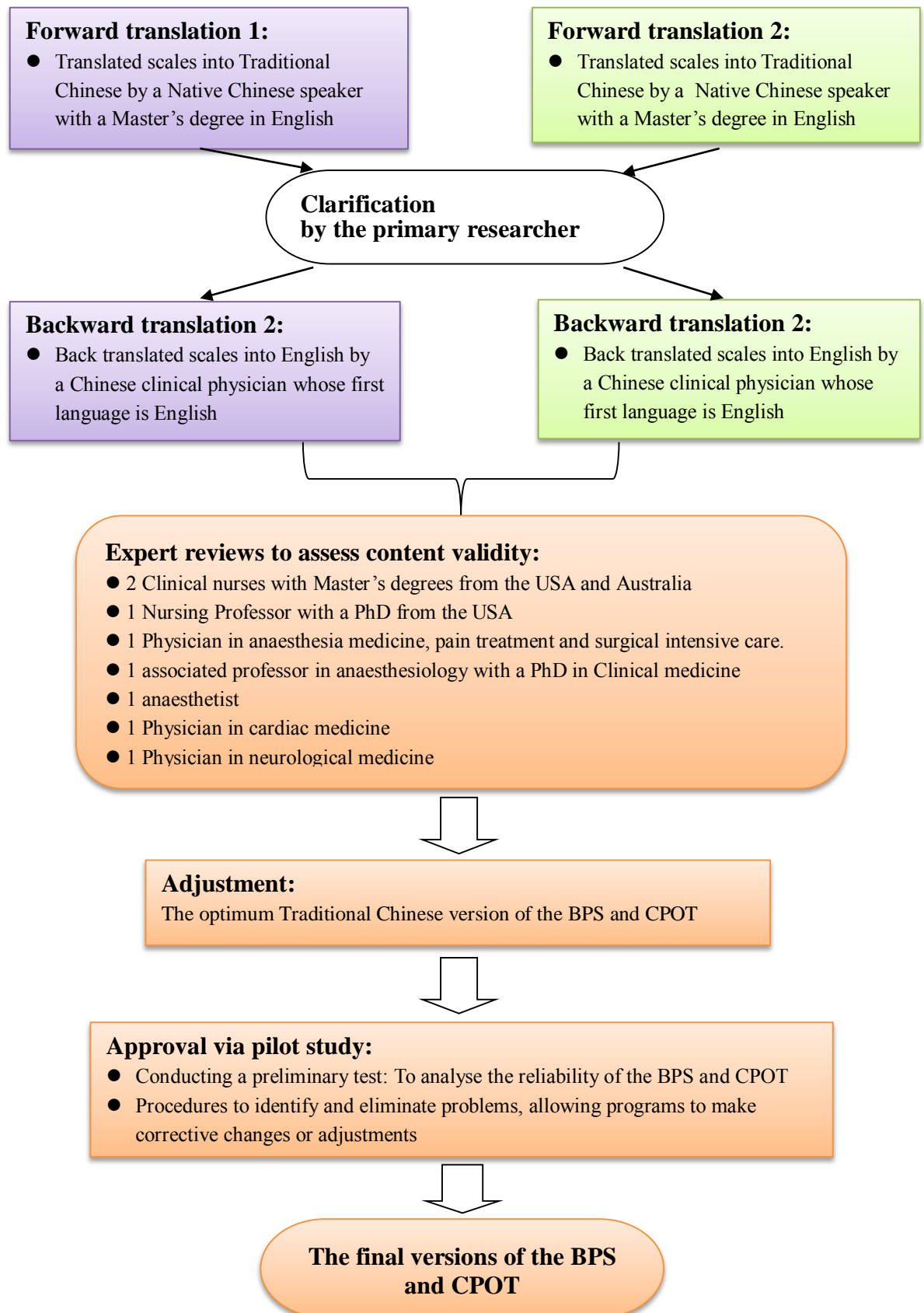


Figure 4.1 Process of translating pain scales

4.4.1 Materials

4.4.1.1 Behavioural Pain Scale (BPS)

The BPS was developed to assess pain in unconscious, mechanically ventilated patients by Payen et al. (2001). It is based on the total score of three behavioural expressions: 1) facial expression, 2) upper limb movements and 3) compliance with mechanical ventilation. The BPS allows assessors to derive a score between 3 (no pain) and 12 (the highest pain score) (Table 4.1).

Table 4.1 The Behavioural Pain Scale

Item	Description	Score
Facial expression	Relaxed	1
	Partially tightened (e.g. brow lowering)	2
	Fully tightened (e.g. eyelid closing)	3
	Grimacing	4
Upper limbs	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Compliance with ventilation	Tolerating movement	1
	Coughing with movement	2
	Fighting ventilator	3
	Unable to control ventilation	4

(Payen et al. 2001)

4.4.1.2 Critical-care Observation Tool (CPOT)

The CPOT, developed by Gélinas et al. (2006), originally written in French, has been translated and validated in countries outside Canada (Chen et al. 2011a,

Kwak & Oh 2012, Marmo & Fowler 2010, Nürnberg Damström et al. 2011, Vazquez et al. 2011, Wibbenmeyer et al. 2011). It consists of 4 components, each with different behavioural categories: 1) facial expression, 2) body movements, 3) muscle tension, and 4) compliance with the ventilator for intubated patients or vocalization for extubated patients with critical illness (Table 4.2). It includes 4 behaviours rated on a 0-2 scale, making a possible total score ranging from 0-8. Behaviours are rated based on the intensity of the reaction observed as described by the author (Gélinas 2006).

Table 4.2 The Critical-Care Observation Tool

Indicator	Description	Score	
Facial expression	No muscular tension observed	Relaxed, neutral	0
	Presence of frowning, brow lowering, orbit tightening, and levator contraction	Tense	1
	All of the above facial movements plus eyelid tightly closed	Grimacing	2
Body movements	Does not move at all (does not necessarily mean absence of pain)	Absence of movements	0
	Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements	Protection	1
	Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed	Restlessness	2
Muscle tension Evaluation by passive flexion and extension of upper extremities	No resistance to passive movements	Relaxed	0
	Resistance to passive movements	Tense, rigid	1
	Strong resistance to passive movements, inability to complete them	Very tense or rigid	2
Compliance with the ventilator (intubated patients)	Alarms not activated, easy ventilation	Tolerating ventilator or movement	0
	Alarms stop spontaneously	Coughing but tolerating	1
	Asynchrony: blocking ventilation, alarms frequently activated	Fighting ventilator	2
OR Vocalization (extubated patients)	Talking in normal tone or no sound	Talking in normal tone or no sound	0
	Sighing, moaning	Sighing, moaning	1
	Crying out, sobbing	Crying out, sobbing	2
Total, range (Gélinas et al. 2006)			

4.4.2 Procedures for translation

4.4.2.1 Forward translation

Permission to translate into Chinese-language versions of the BPS and CPOT was granted respectively by Dr. Payen and Dr. G  linas. The BPS and CPOT were independently translated from their original language (English) into Traditional Chinese by two native Taiwanese, bilingual in both English and Mandarin. The initial translations were carried out independently of each other and at no point in time were the translators in communication with each other. One translator holds a Master's degree in Linguistic Studies, while the other has a PhD degree in Biochemistry. The participation of another linguistic expert during the verification process, along with the primary researcher acted to ensure the comprehensibility of the translated scale for the nurses. Each translation was further refined and a summary of the adjustments compiled. The final translated scale was sent to the general project coordinator, who indicated no further adjustments were required. Additionally, the Traditional Chinese versions of the BPS (Chen et al. 2011a) and CPOT (Chen et al. 2011b) were used (with the consent of the respective authors) as reference material. However, these versions showed insufficient reliability for clinical use.

4.4.2.2 Back-translation

The independent back-translation of the BPS and CPOT into English was achieved by another two Chinese bilingual translators. These translators' native language is English as spoken in the United States. One translator is a medical doctor, who was raised in the USA and received her medical license in Taiwan.

The second translator is bilingual in Traditional Chinese and English and completed her Bachelor and Master's degrees in nursing in the USA. At no time had either of the translators accessed the English CPOT or BPS scales for comparison. Neither had encountered them in their professional life. The scales were then re-submitted to the general project coordinator to assess the potential for any amendments. The back-translated versions of the BPS and CPOT were evaluated by the primary researcher and compared to the English original to identify any discrepancies or inconsistencies in the Traditional Chinese version.

After the translation, the initial content validity of each item was reviewed by two bilingual (English-Mandarin speaking) epidemiologists. They collaborated with the Pain Research Group for semantic equivalence, clarity, and grammatical accuracy. Minor modifications were performed in consultation with two clinical nurses to preserve the semantic and idiomatic equivalence in Traditional Chinese characters for Mandarin-speaking nurses. Words and phrases that might diverge in meaning were compared with the translated version to the original. Where doubts regarding the meaning existed, the problem was discussed with the translator.

4.4.2.3 Expert review

The translated and back-translated versions of the pain scales were submitted to an expert committee of specialists in the subject area. This study then invited reviewers who are experts in different areas of medical practice to assess the initial drafts of the two pain scales for content validity. They evaluated the translations, the amendments and the content validity to produce a pre-final

version of the BPS and CPOT. As part of this process, the relevance of the content validity within the questions was confirmed. A content validity index (CVI) was derived for each item on the two scales. To calculate the CVI, a 4-point scale of item relevance (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant) is used to determine the relevance of the item as per expert opinion (Davis 1992). An acceptable CVI is computed at 0.80, which indicates the percentage of agreement between the experts (Polit & Beck 2006).

4.4.2.4 Adjustments

Based on the specialists' guidance, when the CVI is lower than 0.80, further adjustments are required (Polit et al. 2007). The pre-final versions of the BPS and CPOT were then pilot tested for reliability and repeatability.

4.4.3 Pilot testing

The objective of the pilot study is to establish the practicability and accuracy of the pain scales among the target patient population.

4.4.3.1 Setting and subjects

The pilot study was conducted at the surgical ICU of a medical centre in Hualien, Taiwan. The inclusion criteria for patients were: 1) presence in the ICU for ≥ 24 hours, 2) ≥ 18 years of age, 3) a defined pain locus, i.e. an endotracheal tube, and 4) an inability to communicate verbally. The exclusion criteria were: 1) continuous non-invasive ventilation, 2) cerebral injury, 3) facial injury, 4) arm injury, 5) those receiving muscular blocking agents, or 6) those with muscular

dysfunction due to stroke or tetraplegia. Ten patients participated in the pilot study, which resulted in 40 observations using both the CPOT and BPS scales.

4.4.3.2 Data collection

Approval for this study was obtained from the Institutional Review Board of Tzu Chi Hospital (IRB100-23). As this study did not deviate from routine nursing care, informed consent was not required. The study purpose and procedures were communicated to the involved ICUs via staff meetings.

Patients were observed at two points in time: at rest and during the painful procedure. The painful procedure consisted of endotracheal suctioning of the patient, which has been reported as a painful stimulus (Puntillo et al. 2004, Puntillo et al. 2001, Simons et al. 2003). During a total of 40 independent observations, the patients' pain behaviours were scored based on the BPS and CPOT. Two ICU nurses assessed the patients independently but simultaneously. These nurses attended a 2-hour training session on the use of the BPS and CPOT.

4.4.4 Descriptive analysis

The data were entered into an electronic spreadsheet (Excel®, version 2010), then analysed using simple descriptive statistics performed by SPSS 19.0. The main focus was the content validity of the two pain scale items. Reliability analyses were performed by calculating the inter class correlations (ICC) between the BPS and CPOT scores for independent raters. The Cronbach's α was also examined to assess the internal consistency of the BPS and CPOT. To test validity, this study provides

evidence of content validity by calculating a Content Validity Index (CVI). The ratings for individual items are based on their relevance, as assigned by eight experts.

4.5 Findings

As previously described, the translation of the BPS and CPOT involved a series of stages, comprising: 1) translation, 2) back-translation, 3) evaluation by experts' review, and 4) pilot testing of the pre-final version.

4.5.1 Translation

During the translation, it was necessary to modify several terms between the two translations (versions 1 and 2) in order to maintain their original meaning. Tables 4.3 and 4.4 present the original English version and the discrepancies between the two translations into Traditional Chinese versions 1 and 2 of the BPS and CPOT scales. Several items required alteration in the Chinese version due to semantic, conceptual, and normative equivalences.

Table 4.3 Summary of the differences between versions 1 and 2 made during the translation of the BPS

Indicators	English Original of item's description	Translated Version (Chinese)		Adjustments in Chinese	Reasons
		Translator 1	Translator 2		
Face expression	Partially tightened	部分緊繃	部分緊繃	部分緊繃	Conceptual
	(e.g. brow lowering)	(例如: 眉毛下彎)	(例如: 皺眉)	(例如: 皺眉)	
	Grimacing	痛苦表情	做鬼臉/面部掙掙	做鬼臉/面部掙掙	Semantic
Upper limb	No movement	靜止不動	無活動	無活動	Semantic
Compliance with ventilation	Tolerating movement	可忍受且能移動	可忍受且能順應移動	可忍受且能順應移動	Normative

Different wordings are shown in the bold, purple Chinese characters.

Table 4.4 Summary of differences between translations 1 and 2 made during the translation of the CPOT

Indicators	Original Version of item's description (English)	Translated Version (Mandarin)		Adjustments to Mandarin	Reasons
		Translator 1	Translator 2		
Facial expression	No muscular tension observed (Relaxed, neutral)	無 察覺 肌肉 張力 (放鬆，自然)	無 明顯 肌肉 緊繃 (自然放鬆) (放鬆，自然)	無 明顯 肌肉 緊繃 (自然放鬆) (放鬆，自然)	Semantic
	Presence of frowning, brow lowering, orbit tightening, and levator contraction	出現皺眉，眉毛下彎， 眼眶緊繃，眼瞼肌收縮之表情	前額皺紋，皺眉， 雙目緊睜 ，快速眨眼	出現皺眉，眉毛下彎， 雙目緊睜，眼瞼肌收縮之表情	Semantic
	All of the above facial movements plus eyelid tightly closed (Grimacing)	含上述表情及 眼瞼緊閉(痛苦表情)	含上述 臉部表情及雙目緊閉(面部扭曲)	含上述 臉部表情及雙目緊閉(面部扭曲)	Semantic
Body movements	Does not move at all	靜止不動	完全不活動	靜止不動	Conceptual

Different wordings are shown in the bold, purple Chinese characters.

Table 4.4 SUMMARY OF DIFFERENCES BETWEEN TRANSLATIONS 1 AND 2 MADE DURING THE TRANSLATION OF THE CPOT (Continued)

Indicators	Original Version of item's description (English)	Translated Version (Mandarin)		Adjustments to Mandarin	Reasons
		Translator 1	Translator 2		
Body movements	Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed (Restlessness)	拉管，嘗試坐起，移動四肢/敲打，無法接受指令，攻擊照護人員，嘗試爬下床 (身體隨時都在移動)	拔管，嘗試坐起，移動四肢/揮舞，拒絕配合治療，攻擊醫護人員，設法離開病床 (坐立不安)	拔管，嘗試坐起，移動四肢/揮舞，拒絕配合治療，攻擊醫護人員，嘗試爬下床 (坐立不安)	Semantic Conceptual
Compliance with the ventilator (intubated patients)	Asynchrony: blocking ventilation, alarms frequently Activated	呼吸阻斷，警報時常響起	不同步：警報常常響起，呼吸不時受阻	不同步：呼吸阻斷，警報常常響起	Normative
Vocalization (extubated patients)	Talking in normal tone or no sound	說話聲調正常或是沒聲音	說話正常，無異常聲	說話聲調正常或是沒聲音	Semantic

Different wordings are shown in the bold, purple Chinese characters.

4.5.2 Back-translation

During the back-translation of the BPS and CPOT, no items required alteration. The scales retained the meaning of the original versions. Both scales were checked for words and phrases that might imply a divergence in meaning when comparing the back-translated version with the original.

4.5.3 Expert review

This expert committee consisted of: two clinical nurses, a nursing professor, a medical physician, a surgical physician in neurological medicine, an anaesthetist, an associate professor in anaesthesiology, and a physician in anaesthesia medicine specialising in pain treatment and surgical intensive care. Agreement was achieved for all items concerning their relevance, as well as the definitions of all items in the BPS and CPOT. The item Facial expression, for both the BPS and CPOT, achieved complete consensus concerning its relevance (Tables 4.5 and 4.6). The CVI was greater than 0.80 for all items on the BPS and CPOT, thereby showing satisfactory agreement. The pre-final version of the BPS and CPOT that was obtained at this stage was then pilot tested.

Table 4.5 Expert agreement (n=8) on the items in the Chinese versions of the BPS concerning content validity (relevance and definition) and acceptability of the scale

Items	Pain Score	Relevance				Definition				Acceptability			
		Score*											
		4	3	2	1	4	3	2	1	4	3	2	1
BPS													
Facial expression		8	0	0	0	8	0	0	0	8	0	0	0
Relaxed	1	8	0	0	0	8	0	0	0	8	0	0	0
Partially tightened (e.g. brow lowering)	2	8	0	0	0	8	0	0	0	8	0	0	0
Fully tightened (e.g. eyelid closing)	3	8	0	0	0	8	0	0	0	8	0	0	0
Grimacing	4	8	0	0	0	8	0	0	0	8	0	0	0
Upper limbs		8	0	0	0	3	4	1	0	7	1	0	0
No movement	1	8	0	0	0	8	0	0	0	8	0	0	0
Partially bent	2	8	0	0	0	3	4	1	0	7	1	0	0
Fully bent with finger flexion	3	8	0	0	0	8	0	0	0	8	0	0	0
Permanently retracted	4	8	0	0	0	8	0	0	0	8	0	0	0
Compliance with the ventilator		6	2	0	0	8	0	0	0	7	1	0	0
Tolerating movement	1	8	0	0	0	8	0	0	0	8	0	0	0
Coughing with movement	2	6	2	0	0	8	0	0	0	7	1	0	0
Fighting ventilator	3	6	2	0	0	8	0	0	0	8	0	0	0
Unable to control ventilation	4	8	0	0	0	8	0	0	0	8	0	0	0

**1= not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant. The level of agreement was set to no more than one panel member scoring an item at less than 3.*

Table 4.6 Expert agreement (n=8) on the items in the Chinese versions of CPOT concerning content validity and acceptability of the scale

Items	Pain Score	Validity								Acceptability			
		Relevance				Definition							
		Score*											
		4	3	2	1	4	3	2	1	4	3	2	1
CPOT													
Facial expression													
No muscular tension observed	0	8	0	0	0	8	0	0	0	8	0	0	0
Presence of frowning, brow lowering, orbit tightening, and levator contraction	1	8	0	0	0	8	0	0	0	8	0	0	0
All of the above facial movements plus eyelid tightly closed	2	8	0	0	0	8	0	0	0	8	0	0	0
Body movement													
Does not move at all (does not necessarily mean absence of pain)	0	5	3	0	0	8	0	0	0	6	2	0	0
Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements	1	8	0	0	0	8	0	0	0	8	0	0	0
Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed	2	5	3	0	0	8	0	0	0	6	2	0	0
Muscle tension													
No resistance to passive movements	0	3	4	1	0	8	0	0	0	2	5	1	0
Resistance to passive movements	1	4	3	1	0	8	0	0	0	2	5	1	0
Strong resistance to passive movements, inability to complete them	2												
Compliance with the ventilator (intubed)													
Alarms not activated, easy ventilation	0	7	1	0	0	8	0	0	0	7	1	0	0
Alarms stop spontaneously	1	8	0	0	0	8	0	0	0	8	0	0	0
Asynchrony: blocking ventilation, alarms frequently activated	2	7	1	0	0	8	0	0	0	7	1	0	0

*1= not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant. The level of agreement was set to no more than one panel member scoring an item at less than 3.

4.5.4 Pilot study results

This study highlights the importance of using the most appropriate instrument to collect the intended data for pain assessment in a purposed population. The selection of a scale that matches the research purpose and the data required must be the primary consideration in the process of identifying or developing a pain assessment scale. Altering the appropriate scales is the primary focus within the greater context of the main study. The use of a pilot study allowed a preliminary assessment to be made of the potential for the validation of the Chinese versions of the BPS and CPOT.

4.5.4.1 Patients' profile

Ten participants were recruited for the pilot study by using purposeful sampling (Table 4.7). Five men and five women with a median age of 66 years (ranging from 40-84 years) with variable diagnoses were selected. Sedative and analgesic agents were administered according to the physician's orders and were not standardised for the purpose of this pilot study.

Table 4.7 Description of the characteristics of the patients involved in the pilot study.

ID	Sex	Age	Diagnosis	Apache II	Sedation (daily dose)*	Analgesia (daily dose) [#]
1	M	49	Hepatocellular carcinoma	25	Lorazepam (7.9 ml)	Fentanyl (0.81 ml)
2	F	77	Pneumonia	26	Lorazepam (7.1 ml)	Fentanyl (0.76 ml)
3	M	58	Acute pancreatitis	29	Lorazepam (35.0 ml)	Fentanyl (3.47 ml)
4	M	84	Pneumonia	28	None	Fentanyl (0.70 ml)
5	M	48	Septic shock	24	None	Fentanyl (0.20 ml)
6	M	48	Gastrointestinal Bleeding	19	None	Fentanyl (2.46 ml)
7	F	69	Respiratory failure	31	Lorazepam (19.0 ml)	Fentanyl (2.02 ml)
8	F	40	Respiratory failure	32	Lorazepam (19.7 ml)	Fentanyl (1.98 ml)
9	F	41	Pneumonia	26	Lorazepam (22.5 ml)	Fentanyl (2.18 ml)
10	F	69	Acute pyelonephritis	23	Lorazepam (23.4 ml)	Fentanyl (1.19 ml)

M-male; F-female

Apache II- Acute Physiology and Chronic Health Evaluation (an integer score from 0 to 71 is computed based on several measurements; higher scores correspond to more severe disease and a higher risk of death

** IV infusion; [#] Intermittent IV doses.*

4.5.4.2 Scale validation

This pilot test collected patient's pain scores at rest and during the suction procedure. The results show a 100% increase in pain scores using BPS to rate pain, versus a 90% increase in pain when rating pain with CPOT (Table 4.8). The median scores increased from at rest (BPS=4, CPOT=1) to during ETS (BPS=5, CPOT=2).

The BPS scores are similar to those obtained for the CPOT. The internal consistency of the BPS (Cronbach's $\alpha=0.744$) and CPOT (Cronbach's $\alpha=0.697$) was established based on the ten subjects. None of the items on either the BPS or CPOT based on their relevancy, required elimination. The alpha could not be improved by the deletion of any item. As such, the reliability could not be substantially improved and the scale was not further altered (Table 4.9).

Table 4.8 Distribution of BPS and CPOT scores during each assessment in the pilot study ($n=10$).

ID	BPS (scored 3-12)		CPOT (scored 0-8)	
	Rest	ETS*	Rest	ETS*
1	3	6	0	3
2	4	5	1	3
3	4	5	1	2
4	4	6	1	2
5	4	4	1	1
6	4	4	0	2
7	4	5	2	3
8	3	4	1	2
9	3	5	0	2
10	4	6	1	4
Median	4	5	1	2

**ETS-endotracheal suctioning*

Table 4.9 Internal consistency of the BPS and CPOT scores during the painful procedure during the pilot study (n=10).

Internal consistency	Cronbach's α (Total items)	Mean if Item Deleted	Variance if Item Deleted	Item-Total Correlation	Cronbach's α if Item Deleted
BPS	0.744				
Facial expression		8.15	2.555	0.474	0.723
Upper limbs		9.15	2.239	0.542	0.684
compliance with the ventilator		9.70	2.958	0.457	0.755
CPOT	0.697				
Facial expression		4.40	2.463	0.542	0.618
Body movement		5.15	2.345	0.562	0.605
Muscle tension		4.80	3.011	0.355	0.629
compliance with the ventilator		5.60	3.305	0.075	0.749

4.6 Summary

It was a necessary to adapt several terms in the Chinese version in order to retain the original meaning of the BPS and CPOT. Important modifications were necessary in the forward translation of both scales as a result of the need to validate the cross cultural and language differences. These modifications consisted of: 1) selecting the term, wording, and verb tense for conceptual accuracy 2) assessing the consistency of the medical care staff and their accurate use of these scales to assess pain. This process ensured that the survey collected high quality, generalisable data for the project and could uncover useful information from the respondents (Boynton 2004).

Tables 4.8 and 4.9 present the results of the pilot test. In general, the BPS and CPOT were reported to be comprehensive and well-formatted for ease of use on the ward.

The Cronbach's α 's reliability of the 3-item measure of the BPS was 0.744 and, for the 4-item measure of the CPOT, it was 0.697. In Table 4.8, the item that had the greatest effect on the BPS appears to be item II (Upper limbs), with $r=0.542$. Similarly, the most influential item on the CPOT is item II (Body movements), with an item-total correlation of $r=0.562$. Although the item with the lowest item-total correlation for the CPOT is item IV ($r=0.075$), it was retained, as "compliance with ventilation" remains an important pain indicator. Item III (compliance with the ventilator) in the BPS and item IV (compliance with the ventilator) in the CPOT are extremely important and easily recognisable visual pain indicators. To assess the effect of the deletion of this item on the overall Cronbach's α of both scales, the reliability analysis was recalculated. The Alpha-if-item-deleted values are both greater than the overall alpha, which suggests that these items are irrelevant to the scales. The study re-ran the reliability analysis with various items removed for comparison. However, when items I and II in the BPS or items I, II and III in the CPOT were removed, the overall alphas of the BPS and CPOT both decreased. As this study relies on accepted scales obtained from a published source, it is possible to compare the results with those of other researchers using the same scale.

The Traditional Chinese versions of the BPS and CPOT have been shown to be useful scales for the bedside assessment of pain amongst NVCPs. The validity of this scale for pain management amongst the Chinese population requires further study in order to enhance its implementation within the hospital system. The limitations of this study include the self-evident fact that patients who cannot communicate their experience of pain are at the mercy of the nurse's careful observation. A study of both pre- and post-pain experiences within the medical system will produce a greater understanding of

the patient experience and facilitate improved pain management. Consistent with previous studies, the BPS and CPOT items were responsive to painful procedures in the pilot study. The findings of the present study suggest that the Chinese version of BPS and CPOT can be recommended as an instrument for assessing pain in critically ill adults. In order to achieve enhanced generalized use of these scales, further evaluation of the BPS and CPOT in critically ill patients is required. The full study with a large population of NVCPs will be presented in the following chapters.

Chapter 5: Phase 2: Validation of pain scales in target Patients

5.1 Introduction

This chapter consists of a report of the full validation of the Behavioural Pain Scale (BPS), Critical-care Pain Observational Tools (CPOT), and the Face Rating Pain Scale (FRPS), to assess nonverbal patients' pain with sedative and ventilated treatment. The research question evaluates the reliability and validity of the responses using the BPS, CPOT, and FRPS when used to rate pain from a non-painful stimulus and a painful stimulus in NVCPs. In previous pain assessment studies involving NVCPs, their experience is evaluated using a single scale measurement. This study involves three pain scales where the evaluation methodology is a fundamental component of the research design.

As part of the scale translation, content validity is addressed by basing the items on the previous review of the pain scales by a panel of experts experienced in pain management (Polit et al. 2007). This study also employed a small pilot study to test the reliability and validity of the three study scales in phase 1. However, the premise of using a pilot study to conduct reliability testing may be insufficient to validate the scale due to a degree of random error (Bannigan & Watson 2009). Based on the strong results for reliability and validity obtained from the pilot study, a large study is necessary to extrapolate for generalisability to Chinese speaking populations.

This methodological study expanded upon the pilot study conducted in phase 1 in the surgical and neuro-intensive care unit of one of the system's hospitals. Reliability and validity were further examined based on 2,068 observations of 237 patients from five

hospitals in Taiwan. Internal consistency was conducted to determine the degree to which each item within a construct was associated. The reliability of each resultant factor was computed using Cronbach's α coefficient. Construct validity was examined through discriminant analysis and correlational analyses. The responsiveness of the pain scales' evaluation criteria to both a painful and non-painful stimulus; suggests that the research can collect and analyse data from both procedures using the same tool, as recommended by Trochim (2006). In order to allow for inferences with a high degree of internal validity, highly controlled true experimental designs (i.e. randomised, single blind) must be inherent during the design and implementation of the scientific study (Brewer 2000). The remainder of this chapter details the processes of the research, which constitutes phase 2 of the validation of the three pain scales.

5.2 Background

Test and scale developers are responsible for ensuring that assessment products and services meet both professional and technical standards, as well as legal requirements (Joint Committee on Testing Practices 2004). They also have a responsibility for providing technical documentation about their tests, including evidence of reliability and validity that supports inferences drawn from the test scores. To use measurement instruments in clinical practice, the extent to which they are reliable, valid and usable is often described by their psychometric properties, such as validity, reliability, and responsiveness (Diehr et al. 2005). Reliability encompasses the concepts of internal consistency, stability and equivalence. There are many different types of validity, including the concepts of content, face, criterion, concurrent, predictive, construct, convergent (and divergent), factorial and discriminant (Bannigan & Watson 2009).

Factor analysis continues to be a central tool for discerning the validity and reliability of scales that might be used in business decisions (Bartholomew et al. 2008). However, the constructs of the BPS, CPOT, and FPRS with fewer than five strongly loading items are insufficient for examining the impact a factor may have on the scales (Costello & Osborne 2005). The following discusses which types of reliability, validity, and responsiveness will be used to evaluate the pain scales to achieve the study goals.

5.2.1 Reliability

Reliability can be assessed based on various factors: stability, internal consistency, and equivalence (Bannigan & Watson 2009). Test-retest reliability is a measure's stability obtained by administering the same test twice over a period of time to a group of individuals. However, test-retest methods may be problematic in the assessment of physical activity, due to intra-individual variation (Steriner & Norman 2008, McCrae et al. 2011). The condition of acute pain in patients is often unstable. This may be exacerbated due to the progression of disease, positioning in the bed, various treatments, and other factors. Patients may undergo multiple treatments or experience confounding factors which can affect their physiological data over the intervening period and produce different results in the second test. To emphasize, the scales in this study focus on the property of the objective measurement of a patient's pain intensity. Due to the temporal nature and subjective experience of pain, it is difficult to assess stability in large populations. These issues must be considered in the study design, as a stability index may be inappropriate for assessing unenduring characteristics such as subjective experiences of pain. It is known that patients' experience of pain varies as a result of their fluctuating

condition over time. This study collected data from two nurses, using the same scale, observing the same patient at the same time. This was implemented in order to compare different raters assessing the same patient during the rest, painful and non-painful procedures at two different time points. These data were then analysed to examine inter-item reliability and inter-rater reliability in the Chinese versions of the BPS and CPOT. This was done in order to measure the internal consistency and equivalence, respectively.

It is incorrect to suggest that reliability is one of the fundamentals of pain assessment, as reliability consists of multiple variables. To answer the current research questions (RQ1 and RQ2), inter-item reliability for internal consistency and inter-rater reliability for equivalence are necessary to assess the overall consistency of the three scales. Internal consistency reflects the coherence of the components of a scale but is conceptually independent of retest reliability. Retest reliability reflects the extent to which similar scores are obtained when the scale is administered on the same patient at various points in time (Beattie et al. 2014). Internal consistency is used to test the reliability of the scales as it evaluates the degree to which different test items in the BPS and CPOT evaluate objective pain experience yet produce similar results. A method of measurement or scale is said to have high overall consistency if it produces similar results under the same conditions (Beattie et al. 2014). Polit and Hungler (1995) stated that the less variation an instrument produces in repeated measurements of an attribute, the higher its reliability. A reliable measure is essentially concerned with the degree to which different users of a method of measurement or scale will differ in their assessment of the same subject of interest (McHugh 2012). Inter-rater consistency, which involves the use of the scale by the

same users at the same time, can be explored as a score of homogeneity, or consensus.

5.2.2 Validity

There are many ways to test the validity of a measure: 1) content validity or face validity, 2) concurrent validity or predictive validity for criterion validity, and 3) convergent validity or discriminant validity for construct validity (Bannigan & Watson 2009). However, the types of validity that are necessary to consider during the development of new instruments remain dependent on the construct of interest and study design. Validity is focused on the meaning and interpretation of a scale (Brains et al. 2011, p. 105). A primary goal in developing an adequate new scale is to create a valid measure of an underlying construct (DeVellis 2011). During phase 1 of the study scales development, each study scale was critically reviewed by an expert panel. The expert panel presented their considerations about the content validity and, based on their collective experience, a consensus was reached with respect to the underlying item constructs. In phase 2, the study will apply concurrent and discriminant validity to evaluate the constructs of the BPS and CPOT compared to the FPRS. Criterion validity (often referred to as predictive & concurrent validity) states that; if a test is valid, it should correlate with or predicts some criterion of interest that has been established as valid (Bannigan & Watson 2009). At present, no pain scale exists that has been validated in NVCPs due to the presence of artificial airways or underlying pathologies. The FPRS is one of the most widely recommended pain assessment tools and the most commonly used in Taiwanese clinical practice (Li et al. 2007). The study hypothesised that a significant

correlation could be established between the BPS, CPOT, and FPRS scores respectively when assessing the same patient. By implication, each rater was supposed to assess the same pain. This study applied concurrent validity to assess the difference between observations using the BPS or CPOT compared with the FPRS. The evaluations of the comparisons takes into account both non-painful and painful stimulus and the differences between the pain scales ratings.

A scale can use construct validity to extend our understanding of whether its scores have a strong internal correlation with the scores of other measures in a predictable manner (MacQueen 2010). Construct validity includes: 1) convergent validity, 2) factorial validity, and 3) discriminant validity, which is related to test validity (Kline 2000). The study hypothesises that significant differences exist between different interventions (non-painful or painful) in terms of discriminant validity where the three scales can be used to accurately assess pain from the objective perspective. If an analysis of this study can provide a high degree of discriminant validity, this suggests that the three scales may have dissimilar constructs yet remain valid pain assessment instruments (Bannigan & Watson 2009). This study develops a framework in phase 2 to explore the discriminant validity between the BPS, CPOT, and FPRS. In addition, the study also tests the degree to which the BPS and CPOT correlate with the FPRS for the same interventions, measured at the same time. The current research seeks to augment the scale validity through thorough testing of the underlying constructs and consistency. The proposed methodology gathers data from two sources. The data source is of key importance in ensuring that the data collected is reliable. As such, the two different raters are nurses who will have attended a training and development course on the use of the pain assessment scales.

The nurses will be tested and must demonstrate excellent working knowledge of the pain assessment scales prior to the inclusion of their observations as part of phase 2. This provides an opportunity to establish the reliability of data from one source compared with those from another. The training programme details will be presented in depth in the observer training section of the methods implemented.

5.2.3 Responsiveness

Before being introduced into wide usage, health status instruments must be evaluated for reliability and validity. Increasingly, they are also tested for responsiveness to important clinical changes. A seminal review suggests there are two major aspects of responsiveness, which are "internal responsiveness" and "external responsiveness" (Husted et al. 2000). The properties and interpretation of commonly used internal and external responsiveness statistics are examined. The capacity of a scale to detect meaningful change over time, classically described as responsiveness, involves two issues: 1) the measure must detect meaningful change when it has occurred and 2) it must remain stable when no change has occurred (Streiner & Norman 2008, p.267). This study aims to define a clinically important change in a measure related to corresponding changes in the scale of pain in patients experiencing different pain stimuli. Hence, it is from an interpretive perspective that external responsiveness statistics are considered particularly informative. The usefulness of scales' responsiveness should be quantified using indicators of effect size, and a modified effect size statistic proposed by the index (Guyatt et al. 1987) for assessing external responsiveness is also highlighted. The following section will

explore how the empirical validation of the three study scales will be designed, conducted, and publicly reported for testing the research hypotheses.

5.3 Methods

This section presents the method used in phase 2. The pain assessment tools used in this study had previously been validated for such use as described below. The quantification of the exploration into physiological pain behaviour measures in a comparative-instrument study, involving three different types of comparison instruments, requires accuracy. The research undertaken for this thesis was based on the hypothesis prior to data collection. In this methodology section, the aims, hypotheses, and study design of phase 2 will be presented. An elaboration on the data collection methods employed and an in-depth explanation will follow. The quantitative analysis techniques that will be used are discussed for their relevancy to this mixed methods research.

5.3.1 Aims and hypotheses

The intention of this study is to address the pain assessment accuracy of the BPS, CPOT, and FPRS in the Chinese-speaking population in Taiwan. The purpose of this sequential exploratory design was to obtain quantitative data from a purpose specific patient population. The supporting data was based on the follow-up of nurses' personal accounts to expand on the quantitative results in more depth. At this stage (phase 2), the quantitative hypotheses addressed the validity and reliability of these three instruments for the assessment of pain in critically ill NVCPs. In phase 3, this mixed methods research embedded semi-structured focus group interviews to clarify the participant (nurses) experiences working with the pain scales. The

rationale for the inclusion of qualitative follow-up data is to seek a deeper understanding of the quantitative results from phase 2 of this project (Cerdeira 2005).

This study sought to validate the three instruments (BPS, CPOT, and FPRS) as a means of measuring pain in NVCPs. The answer to the first research objective provided specific items for use in operationalizing pain measurements. This study also predicted that painful stimuli would correlate positively with the pain scores for each dimension and subscale in the three pain assessment scales. Further, this research expected that the BPS and CPOT would be better predictors of pain intensity in the targeted population than the FPRS. In order to define the parameters of the scales in this research, and address RQ2, and RQ3, thirteen research null hypotheses were formulated:

H₁: There is no relationship between sets of items in the BPS.

H₂: There is no relationship between sets of items in the CPOT.

H₃: The agreement is no greater than 0.4 between two independent raters using the BPS.

H₄: The agreement is no greater than 0.4 between two independent raters using the CPOT.

H₅: The agreement is no greater than 0.4 between two independent raters using the FPRS.

H₆: There is no correlation between increase in pain scores when using the FPRS and BPS on the same patient and at the same time.

H₇: There is no correlation between increase in pain scores when using the FPRS and CPOT on the same patient and at the same time.

H₈: There are no differences between pain scores using BPS when patients undergo the painful procedure in comparison to the non-painful procedure.

H₉: There are no differences between pain scores using CPOT when patients undergo the painful procedure in comparison to the non-painful procedure.

H₁₀: There are no differences between pain scores using FPRS when patients undergo the painful procedure in comparison with the non-painful procedure.

H₁₁: There is no association between the non-painful procedure's responsiveness and the painful procedure's responsiveness scores when using BPS.

H₁₂: There is no association between the non-painful procedure's responsiveness and the painful procedure's responsiveness scores when using CPOT.

H₁₃: There is no association between the non-painful procedure's responsiveness and the painful procedure's responsiveness scores when using FPRS.

The purpose of phase 2 was to answer the research questions, defining the items of the subscales that form the basis of the BPS, CPOT, and FPRS. The following will explain the decision making process within the study design.

5.3.2 Settings

A convenience sample of 15 ICUs in five hospitals was proposed and selected in Taiwan. The hospitals are geographically separated across the island with regard to: 1) northern Taiwan, 2) central Taiwan, and 3) southern Taiwan.

Two of the hospitals containing three ICUs, are located in New Taipei city, in northern Taiwan. Hospital A has 1,580 beds, containing 92 ICU beds. It is also an

academic teaching hospital affiliated with a Medical University in Taiwan. Hospital B, also located in northern Taiwan, has 929 beds, a 7-bed Burn care and a 91 bed ICU.

This study also recruited patients from two general practices in central Taiwan. Hospital C, located on the east coast of central Taiwan, consists of five ICUs: a burns unit, a surgical unit, two medical ICUs, and one respiratory care centre (RCC). It provides 1,027-beds, which includes an eight bed burn care and an 87-bed ICU. Hospital D is a rural hospital in central Taiwan. This hospital includes 1023-beds with a 47-bed ICU, containing medical, surgical, neurological, cardiovascular care, trauma, and transplantation units.

In southern Taiwan, the study conducted patient recruitment at hospital E. This hospital is also located in a rural district of Taiwan, and offers an 80-bed long-term care facility and inpatient care for 776 individuals. The inpatient care provides an intensive care service, which includes a 47-bed surgical and medical ICU, a 5-bed burns unit, and a 10-bed RCC.

5.3.3 Sample size

To date, there have been no comparative studies similar to this prospective original research. In order to avoid the type II error, the power of the hypotheses must be tested using a statistically adequate sample size. The procedure for calculating the sample size in this research involves more than two comparison groups, as such, “G Power” statistical software was employed (Faul et al. 2007).

In clinical research, an estimation of the exact sample size may be performed based on understanding various prerequisites (i.e. power analysis, statistical inferences) (Charan & Biswas 2013). To provide an optimal, reliable sample size calculation, it is important to determine the sample size based on an appropriate statistical test (Suresh & Chandrashekara 2012). Power analyses were performed using G Power3. To address the questions of interest in the study design, the effect size (ES) in this study was assessed, at 0.25 (small effect), to be large using Cohen's (1988) criteria. For the validity study, ANOVA repeated measures based on 95% assurance and 80% power, the projected sample size required for this ES is approximately 45 per group for this three-way group comparison. In order to achieve an acceptable degree of statistical inference, the reliability study was based on an independent t-test with an $\alpha=0.05$ and power=0.80. As such, the projected sample size required with this ES is approximately 51 subjects for the reliability group. Thus, the proposed total sample size of 210 will be more than adequate to fulfil the main objective of this study. This will allow for expected attrition, as well as the potential for possible subgroup analysis.

Detecting a true effect or the possibility for generalizability, the power of the sample size must be achieved (Röhrig et al. 2010). The calculated sample size required to satisfy the ES was 210. The study was able to recruit and retain a total of 237 patients for research purposes. Limitations for generalizability exist when relying on a small sample size for data. This can have profound effects on the outcome and validity of a study (Aberson 2010). Satisfying the requirement of the ES sample size, in this research, should facilitate a useful contribution to the understanding of pain in NVCPs.

5.3.4 Criteria for the selection of participants

To select the most appropriate patients to represent the affected population, the criteria must be clearly described (Röhrig et al. 2010). The selection of the target patients for this study is discussed in this section. Patients suffering from critical illness in relation to neuropathy, myopathy, or burns to the face, arms and hands are often unable to communicate via writing, speech (due to tracheostomy) or lip reading (Muthuswamy et al. 2014). Patients' treatment interventions or even their critical illness itself may not only alter their communication ability, but also influence their behavioural expression of pain. This project recruited critically ill patients with diverse diagnoses from various ICUs who met each of the criteria. The patient population for inclusion in the study had to be mechanically ventilated and sedated or unconscious and consequently unable to provide a verbal self-report of their pain. It must be noted that complaints of pain frequently arise after tracheal intubation within the 48 hours post-operation (Biro et al. 2005). To further refine the inclusion criterion, the post intubation period due to surgical intervention was set at greater than 48 hours. The duration of mechanical ventilation was defined as the time from intubation to the time of final extubation. The study also excluded individuals with conditions that would have a confounding effect on the measurement of the primary outcomes of the study. Exclusion criteria were based on the recommendations by Herr et al. (2006) to select a behavioural pain tool in which the patient can be observed exhibiting the categories of pain influenced behaviours (i.e. movement of limbs). The target patient populations were recruited based on the criteria listed in Table 5.1.

Table 5.1 Inclusion and exclusion criteria of target populations

<i>Inclusion criteria</i>	<i>Exclusion Criteria</i>
Aged ≥ 18 years	Receiving neuromuscular blockade
Mechanically ventilated ≥ 48 hours	Quadriplegia
Receiving sedation treatment	Peripheral neuropathy
Haemodynamically stable	A history of severe dementia, psychosis or neurologic disease
	Previous enrolment in a reliability cohort meant exclusion from the validity testing cohort
	Patient or family refusal to participate

5.3.5 Recruitment protocol

A prospective evaluation of purposive patients with critical care was performed from April 20, 2011 to September 30, 2012. After IRB approval was gained (for details, Section 3.6), the contact nursing administrator assisted the researcher in obtaining permission from the chief nurse to conduct the study. To ensure cooperation with healthcare professionals, the manager of the nursing department and hospital was alerted to the study during a meeting of the Research Ethics Committee in each hospital. The participating nurses¹ (PN) provided a full explanation of this research to the family of each patient in the different groups,

¹Participant nurses (PNs) refer to the users of the pain assessment tool with a specialty focus on the observation of the research patients' pain. They were the staff in the study setting but not the clinical nurses for the patients during the data collection. The PNs' role was to ensure patient safety, the ongoing maintenance of informed consent, and the accuracy of data collection, data recording and follow up.

describing the purpose of this study and issuing an invitation to participate where appropriate. As for respecting the participants, confidentiality was assured, and the participants or their family were informed that no extra administration fee would be charged. Patients or at familial request, were free to withdraw from the study at any time.

Recruitment ensured the selection of individuals with the correct criteria to provide adequate statistical power within the planned duration of the study (Walker et al. 2006). In order to address RQ1, RQ2, and RQ3, the study formulated the recruitment process flow chart in relation to the 13 null hypotheses of this quantitative study. Figure 5.1 presents the design of the patients' survey stage.

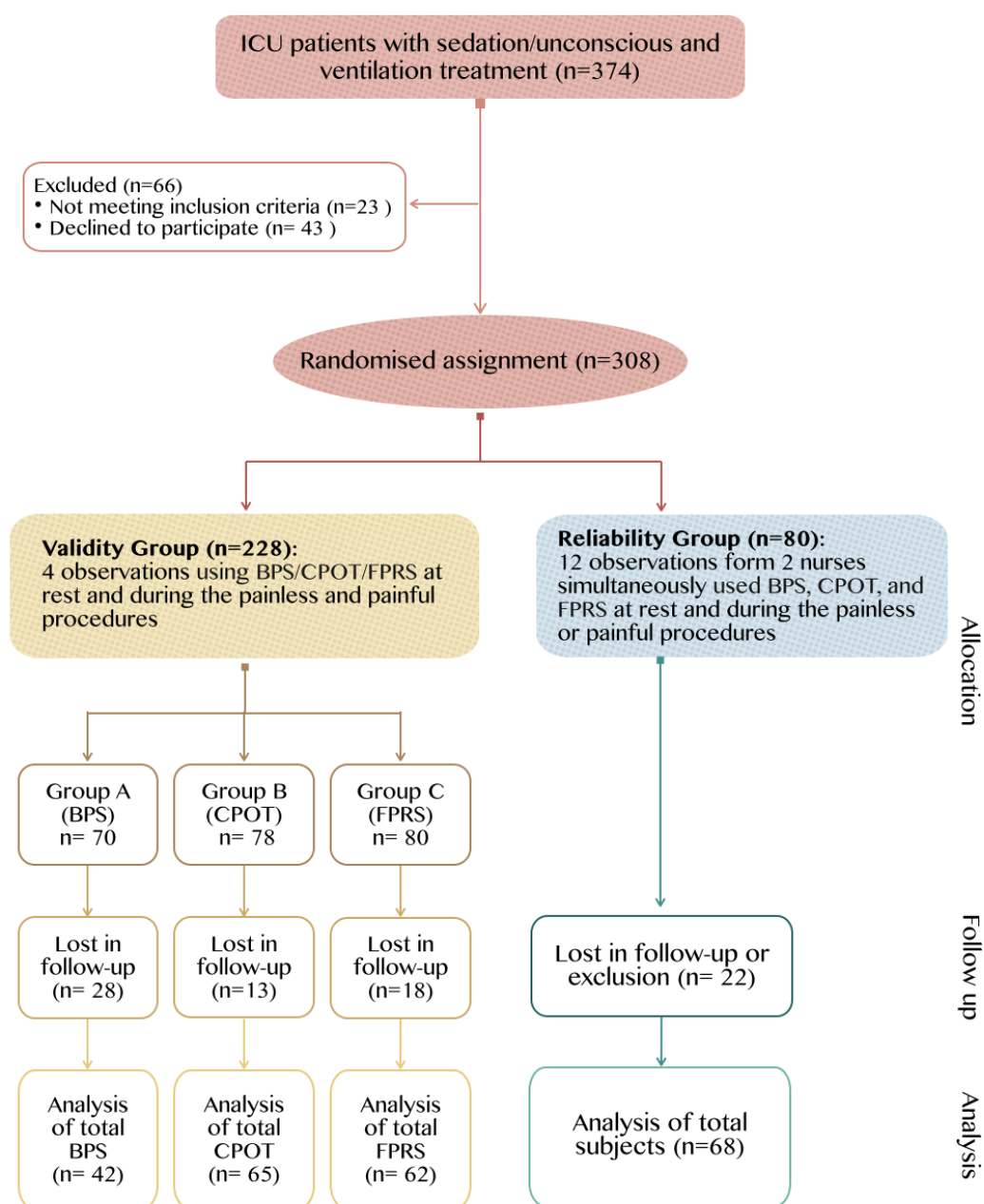


Figure 5.1 Random assignment of patient recruitment in phase 2

Recruitment for the study halted when the IRB approval for the study expired. In order to achieve the sample size, the study reapplied for IRB approval to extend the recruitment period for a further 6 months. A total of 374 patients were targeted for

the study. Of these patients, 17% were excluded and 21% were lost to follow up due to attrition. During the initial screening phase 66 patients were excluded due to failing to meet the inclusion criteria (23 patients) or choosing not to participate further (43 patients). The exclusion criteria most often enforced by the study parameters was the use of neuromuscular blockade (Table 5.1). The second most prevalent reason for the loss of participants was the patients' family's feelings of being intruded upon. In addition, some subjects were moved to different wards during the study and were lost to follow up. At the time of recruitment, an incident involving invasion of privacy within the health care system was at the forefront of the news. This unfortunate event negatively influenced the outlook of many potential participants. These subjects feared that the researchers were being dishonest with respect to the risks associated.

The sampling method of the phase 2 research is based on the purely mechanical randomisation of the target populations into the three groups of interest across the five hospitals (Group A-BPS, Group B-CPOT, and Group C-FPRS). GraphPad software was used for patient assignment and random sample selection from within the target groups at the participating hospitals. To enhance the power of the study, 308 patients were selected for statistical analysis using GraphPad software. The computer software randomly assigned the patients to the validity and reliability groups and a table of different random allocation sequences was generated for the three scales. The patients were assigned to the validity (Group V) or reliability group (Group R) and could not be switched from one group to the other. Similarly, a patient within Group V could only be assigned to one sub-group and could not switch between groups (Group A-BPS, Group B-CPOT, Group C-FPRS). In

accordance with the randomisation, the participating patients in Group R were observed in terms of their pain behaviour using the three pain assessment scales (BPS, CPOT, and FPRS) by two nurses. Due to the nature of the study and the interventions, the potential for bias arising on the part of the subjects and researchers is inevitable (Smith 2008). Unfortunately, using observational scales to assess pain makes it an impossibility to employ double blind method to collect data. Fortunately, the patients selected for the study are sedated or unconscious individuals who remain unaware of their group allocation status. Hence, this research employs the single blind based on the participants which aims at reducing bias in the resulting data analysis. The patients' pain was assessed immediately as the painful procedures were being conducted and then reassessed during the course of the procedure using the three pain scales.

5.3.6 Measurement materials

To analyse the differences between the scores for two interventions; the study design allowed for the collection of potential variables of interest through observations when using the pain scales. The three final Chinese version pain scales (the BPS, CPOT, and FPRS) were used to rate pain behaviour in this sample of patients. In addition to the pain scales data, the effect of potential confounding variables in an analysis cannot be ignored. Based on the research question, participants must be randomly assigned to different treatments (Smith 2008). As this is not feasible in the current study, the data collected included situational characteristics in order to control statistically for their influence on the dependent, or outcome variable. This study identified these variables based on previous epidemiological studies and the

known and possible etiological mechanisms of these diseases and their associated pain profiles (Blakely & Page 2001). Alabas et al. (2012) and Tsai (2007) also stated that age and gender are confounders in practically all studies. Therefore, apart from the data of interest, the patient population characteristics were also collected. This included: 1) age, 2) gender, 3) illness, 4) the severity of the disease and 5) physiological data.

In healthcare, diagnosis codes are used as a tool to group and identify diseases. Diagnostic coding is the translation of written descriptions of diseases, illnesses and injuries into codes from a particular classification. Several diagnosis classification systems have been implemented to various degrees of success throughout the world. The International Statistical Classification of Diseases and Related Health Problems (ICD) is one of the most widely used classification systems for diagnosis coding. ICD allows for comparability and the use of mortality and morbidity data (Steindel 2010). It is the standard diagnostic tool for epidemiology, health management and clinical purposes. This includes the analysis of the general health situation of population groups. In addition, the Acute Physiology and Chronic Health Evaluation II (APACHE II) score is a severity-of-disease classification system and one of several ICU scoring systems (Knaus et al. 1985). It is used to track the diseases and health conditions of patients and has been validated for use in people over the age of 16. APACHE II predictions of hospital mortality show good discrimination and calibration and are useful for benchmarking performance in clinical practice. Additionally, it is applied within 24 hours of a patient's ICU admission: an integer score ranges from 0 to 71. High APACHE II scores correspond to more severe disease and a higher risk of death. In Taiwanese ICUs,

APACHE II is used to measure the severity of the disease for adult patients who are admitted to ICU.

Physiological data on the patient population of interest was collected as previous studies have shown that increased HR and increased MAP are the most frequent physiological indicators of pain (Arbour & Gélinas 2010, Odhner et al. 2003, Puntillo et al. 2001). The hemodynamic variables collected for this study included: heart rate (HR), respiratory rate (RR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP). The multimodal ICU bedside monitor (model and make) and an arterial line with a three lead Electrocardiography were employed. The patients' sedation levels were assessed using the Richmond Agitation Sedation Scale (RASS), which is a ten-item scale. RASS is a Likert scale with a range from unarousable (-5) to combative (+4). RASS has proven satisfactorily reliable and valid when used to assess ventilated or non-ventilated, and sedated or non-sedated adult ICU patients (Hunsley 2008). The patients' altered level of consciousness was also assessed using the Glasgow Coma Scale (GCS). This is determined by assessing three aspects: eye opening (4 levels), verbal response (5 levels) and motor response (6 levels). Tracheal intubation makes it impossible to test the verbal response. In these circumstances, the score assigned is one with a modifier attached e.g. "V1E" where E = endotracheal tube. The score ranges from fifteen for fully alert, to three for the deepest coma. Brain injury is classified as severe, with $GCS \leq 8$. This is a generally accepted definition of a coma. Moderate affect is associated, with $GCS 9 \sim 12$, signalling loss in conscious awareness. Minor loss in cognition is associated with $GCS \geq 13$ (Teasdale & Jennett

1974). This instrument has been demonstrated as an efficient predictor of in-hospital mortality (Lewis 2007).

During the investigation, no protocol to guide either analgesia or sedation existed in the study ICUs. No objective target level of sedation was routinely identified according to the disease state or ventilator settings. The analgesic dose or sedative medications remain dependent on the patient's history of analgesic use, pain scores, and level of sedation. The administration routes were subcutaneous and intravenous infusions. The most common administration route is intravenous, as it quickly provides adequate plasma levels that can be maintained (Morita et al. 2005). All doses of narcotics, benzodiazepines, and propofol were recorded at 8-hourly intervals throughout the investigation. Administered narcotics were the morphine or fentanyl. Administered benzodiazepines were either alprazolam or midazolam. The midazolam dose was converted to alprazolam equivalent by dividing by twenty to achieve an equipotent dose, as alprazolam is twenty times as potent as midazolam (Cammarano et al. 1998)

5.3.7 Study interventions

The research question evaluates the reliability and validity of the responses using the BPS, CPOT, and FRPS for assessing pain in NVCPs. To test the research null hypotheses, two clinical procedures were employed for pain assessment using the three study scales: eye care (EC) and endotracheal suction (ETS). EC, which consisted of a simple eye wash with normal saline and a cotton wool ball, was chosen as the non-painful procedure for this research (Young et al. 2006). The painful procedure was selected based on previous studies. ETS and position changes

have been documented as being the most painful procedures that critically ill patients undergo (Puntillo et al. 2004, Puntillo et al. 2001, Simons et al. 2003). Some studies have used turning as the non-painful procedure to examine pain scales' accuracy. However, Stanik-Hutt et al. (2001) reported significantly higher pain scores during turning for trauma patients compared to trauma patients at rest. No difference was found for non-trauma patients. Therefore, the turning procedure is not selected for inclusion in this study for assessing pain scales' accuracy. In order to avoid interference from any other procedures, ETS was selected as the painful procedure for this study. EC and ETS procedures received during daily standard care in ICUs represented the non-painful and painful procedures in this study. As an ethical consideration, no additional interventions or procedures were performed on the patients for the benefit of the study. As this study is not intended to influence practice, these two procedures were not standardised. Both the painful and non-painful procedures are performed by the health care providers in charge of the patient.

5.3.8 Study procedure

This survey was conducted over an eighteen month period in Taiwan. For each patient, the scores for the three study scales and the physiological variables were collected three times a day by nurses in each ICU study setting. The scores of the BPS, CPOT, and FPRS and the physiological variables were recorded three times a day and it took approximately 15 minutes to collect these data (Figure 5.2). The first data collection period (O_{x1}), which is an observation of the pain level, occurred 10 minutes before the patient underwent the non-painful procedure to provide a

baseline at rest. To assess the pain scales' responsiveness to the stimuli, the second data collection period (O_{x2}) is described as the EC intervention and the third data collection period (O_{x3}) was the ETS procedure. The timing and intervention of each of the procedures performed was based on each individual patient's care needs.

Patient's groups	Patients	Rater	Rest	Non-painful procedure	Painful procedure
Reliability group (Group R)	RM	2 PNs	OA_{x1}	OA_{x2}	OA_{x3}
			OB_{x1}	OB_{x2}	OB_{x3}
			OC_{x1}	OC_{x2}	OC_{x3}

Validity groups

(Group V)

Group A	RM	1 PN	OA_{x1}	OA_{x2}	OA_{x3}
Group B	RM	1 PN	OB_{x1}	OB_{x2}	OB_{x3}
Group B	RM	1 PN	OC_{x1}	OC_{x2}	OC_{x3}

RM = Random assignment of Matched Subjects

O: Observation

x_1 : Patient at rest; x_2 : Non-painful procedure occurs; x_3 : Painful procedure occurs

A: BPS; B: CPOT; C: FPRS

Figure 5.2 The multiple time series data collection.

Each patient was assessed three times (Rest, EC, and ETS) which started forty eight hours post ICU admission. For patients who had undergone surgery, observations were not collected until 24 hours post-operative. For patients who were not ventilated at the time of admission but were ventilated later during their stay, the assessments were made in the first forty eight hours after mechanical ventilation. The participant nurses (PN: see footnote 1) would confer with the clinical nurses²

² Clinical nurse perform professional nursing duties related to the care of general medical-surgical patients during their duty time.

to ascertain when EC and ETS procedures were to be carried out. The PNs would return at those times to observe the patient undergoing the procedure performed by the clinical nurses in charge of the patient.

The PNs observed patients using the pain assessment scales based on the table of random allocation sequences of the three study groups (Group A=BPS, Group B=CPOT, Group C=FPRS) and Group R (the reliability group). PNs were not assigned or randomised but established on a convenience basis. PNs assessed the patient at the three predefined times, with at least a twenty-minute interval between EC and ETS. The choice and timing of the procedures were based on the patient's needs. For reliability, observations were made by two PNs to assess the inter-rater agreement. The two PNs were selected based on availability and convenience in the SICU of the medical centre. PNs independently observed patients using the three pain scales (the BPS, CPOT, and FPRS) to assess the patients' pain-related behaviour during each procedure. They made their assessments simultaneously but without communicating with each other. The PNs were not randomised, for reasons of convenience.

5.3.9 Performing observations

As medication may compromise the expression of pain behaviour, the patients were evaluated before and at the peak effect of any analgesic agent they received. The patients were observed during painful procedures to detect any changes in their behaviour. The PNs observed the patients' face and body to note any visible reactions for a period of a minute. During the procedure, the PNs assessed the patients' pain, while the clinical nurses performed EC or ETS. The PNs observe the

patients' face to note any reactions such as frowning or grimacing. These reactions might be brief or extended. The PNs also observed the patient for upper limb movement (the BPS) or body movement (the CPOT). The PNs noted protective movements, such as patients reaching for or touching the pain site (i.e. surgical incision, injury site). In the mechanically ventilated patients, the PNs must pay attention to alarms and the cessation of ventilation due to patient non-compliance. If changes in muscle tension were observed, the PNs were alerted to the patients resisting ventilation movement.

When using the CPOT to rate pain, muscle tension must be evaluated last. This is especially important when the patient is at rest, as the stimulation of touch alone may lead to behavioural reactions. The clinical nurses performed ETS and, a minute later, the PNs performed the passive flexion and extension of the arm. This is done by supporting the elbow in one hand and using the other to hold the patient's hand. The PN performs a passive flexion and extension of the upper limb, and rates any resistance exhibited by the patient. It should be noted that, for the ETS procedure, the item "compliance with the ventilator" in the BPS and CPOT was scored by the PN after the suction procedure was completed. This is necessary, as stimulation by the catheter itself may lead to a coughing reflex and a change in facial expression. The following section describes how the training courses for the PNs ensured that they used the BPS, CPOT, and FPRS accurately.

5.3.10 PN training

Expert opinions that provide input for a situation analysis is an effective method for identifying issues of relevance (Ritzer 2009). External expert informants can be

accessed in order to extend the researcher's range and depth in situations where the primary researcher may not be present. They can also help the researcher to cross check the information obtained from other informants or practices (Lavrakas 2008). Key informants are defined as a particular subject with rich information on the matter under investigation (Patton 2002). This study used a homogeneous purposeful sampling in the ICU setting, identifying nurses as the key informants for the study. The Registered Nurses (RNs) were selected for their capacity as experienced practitioners in clinical nursing and intensive care. These RNs are referred to as PNs and were selected based on the following inclusion criteria: 1) staff RN in the study setting; 2) full-time employment within the hospital ICU for a minimum of a year at the time of data collection. A total of 21 PNs participated in the training course for this study.

PNs were selected from a list of nurses in the Nursing Departments from five hospitals encompassing 15 ICUs. Twenty five nurses were contacted by the principal investigator, and the project and its objectives were explained. Letters were sent to the identified key informants inviting them to take part in the study. Information on the project, its objectives, and their role as raters, and the schedule and venue for the training programme were provided. Written informed consent was signed prior to the actual interview in the second stage of this study. After consent had been obtained, the researcher gave the participants a copy of the final Mandarin version of the BPS and CPOT in advance of the training course. Identified PNs who were absent or on vacation were excluded, as were those solely engaged in administrative activities. Four identified PNs were excluded. The key PNs comprised eight nurses (38%), five nursing specialists (24%), and eight head nurses

(38%) from 15 ICUs in five hospitals. Their ages ranged from 20-59 years, and all were registered nurses who had been working in an ICU for a minimum of two years.

To standardise the data collection method and reduce bias, a two hour training programme was designed and delivered by the principal investigator. The content of the training programme included: 1) an introduction to pain assessment, 2) the content of the Face Pain Rating Scale (FPRS), 3) the Mandarin version of the BPS and CPOT (i.e. operational definition of each item), 4) standard procedures for using the three scales, 5) a detailed description of the scoring method, and 6) the patient's data. Following the training, PNs performed a supervised clinical practice to establish whether the scales were satisfactorily understood. The principal investigator and the PNs independently scored an ICU patient using the three scales in accordance with the study protocol: 1) rest; 2) eye care; and 3) endotracheal suctioning. This process was repeated until an agreement of 100%, using the CPOT, BPS and FPRS was met for both the principal investigator and the PNs. A total of 21 assessments on three separate occasions was necessary to reach 100% agreement.

The possibility of adjustments was retained should 15% or more of the PNs have difficulty comprehending or answering an instrument item (Herdman et al. 1998). After obtaining permission from ICU patients' relatives, PNs practiced using the Chinese version of the BPS and CPOT within medical ICUs. Before and during the test procedures, PNs observed patients' pain-related behaviour and independently completed the FPRS, BPS and CPOT. The proportion of PNs who failed to answer a question satisfactorily ranged from 2-12%. This indicated that it was unnecessary to adjust the questionnaire. In order to maintain consistency of the data collection,

any concerns or questions related to the scales were to be openly communicated to the primary investigator. A small group discussion was conducted to establish the content and contexts of the items on the scales and to clarify the PNs' questions about the data collection.

To explore the perceptions of the PNs when using the three scales, they were invited to participate in the focus group discussions. This aspect of the study is important for collecting qualitative data from the perspective of the nurse using the pain scales. These PNs were invited to participate in phase 3 and, similarly, in the focus group

5.3.11 Data analysis

Determining the effectiveness of the three pain scales is the main research question, so analyses and comparisons were sequentially adopted in phase 3. The following includes a description of the analyses of the quantitative data in phase 2, including any relationship that can be established as being significantly related to the presence (or lack) of pain.

A psychometric analysis of the three pain scales used in this study was carried out. For a test to be valid, or truthful, it must first be reliable. Based on the analysis in Section 5.2, each of the questionnaires was then individually examined based on a set of common criteria: 1) reliability: internal consistency and equivalence, 2) validity: discriminant validity, concurrent validity, and responsiveness. Due to confounding variables with respect to specific issues related to the theory underpinning each of the scales as well the concepts presented in Chapter 2, careful consideration of the type of analysis is crucial.

Statisticians work with the descriptive analysis of subjects and multiple types of validity and reliability. To understand the demographic characteristics of the NVCPs, descriptive statistics were used in this study. For there to be a significant comparison, a one-way ANOVA was used to test for demographic differences between the NVCP groups. NVCPs who attained a mean value that did not differ within the group at $p < 0.05$ were clustered. Based on the analysis in Section 5.2, construct validity was evaluated by correlating the BPS and CPOT versus the FPRS domains as concurrent validity, and comparing known groups based on the non-painful and painful status as discriminant validity. To assess sensitivity to change, subsamples of patients in the non-painful procedure and painful procedure were defined, respectively, according to changes in their pain scores by the use of the pain scales.

Internal consistency and inter-rater consistency for testing the reliability of the study instruments are mandatory. Internal consistency is an indication of how the items within the BPS and CPOT are inter-related. Cronbach's α statistic was employed to assess their internal consistency (van Teijlingen et al. 2001). Theoretically, if a scale has high internal consistency, it will have a high Cronbach's α . A commonly accepted internal consistency using Cronbach's α is a value greater than 0.7 (Field 2005). Inter-rater reliability, known as inter-rater agreement, is the degree of agreement amongst raters. This was determined for the BPS, CPOT, and FPRS by obtaining similar measures with different assessors (PNs) using the intra-class correlation coefficient (ICC) and weighted κ indices with 95% confidence intervals (CI) (Friedman 2013). The ICC can range from zero (no agreement) to 1.0 (perfect agreement). In the field of statistics, a value greater than 0.8 is regarded as

satisfactory (Friedman 2013). The data for each scale and their subscales were pooled by the two PNs to estimate the ICCs separately. A 95% CI for the coefficient was derived.

One of the research aims was to investigate whether each study scale could measure an increase in pain after the painful procedure and demonstrate no change after a non-painful procedure. This study hypothesised that, if the BPS, CPOT or FPRS accurately measure pain, the scores would be much higher during the painful procedure compared to the non-painful procedure or while the NVCP was at rest. To assess sensitivity to change, the only conditions included were those where an increase in pain scores could be expected (i.e. post the painful or non-painful procedure). Wilcoxon paired tests for non-parametric variables were used. In addition, responsiveness refers to an instrument's ability to measure small but important changes over time in the concept being assessed, (Lavrakas 2008). Wilcoxon paired tests can use the effect size to detect the magnitude of the property. This coefficient is calculated by dividing the difference between the mean BPS, CPOT or FPRS scores at rest and during the painful procedure by the SD of the mean scores at rest. As the responses to the BPS, CPOT, and FPRS were ordinal variables, daily dosage of medication and physiological pain results were the interval variables. To analyse these mixed variables, the Multi-trait Multi-method Matrix (MTMM) with Spearman nonparametric coefficient was used to calculate whether the associations between the dependent and independent variables are either ordinal numeric or a continuous variable (Hauke & Kossowski 2011). If there are no repeated data values, a perfect Spearman correlation of +1 or -1 occurs, showing a proportional linear relationship. Accounting for similarity in content, the MTMM

was hypothesised to be moderate (0.4-0.6) between some of the BPS, CPOT subscales and FPRS scores. The mean scores were compared with the ANOVA and the magnitude of the difference between the groups and the procedures was further quantified by an effect size coefficient (Thabane et al. 2010).

Statistical analyses were performed using SPSS version 19.0 software. Quantitative variables were presented using means and SDs for continuous variables which included interval and ordinal variables. Frequencies and proportions for dichotomous variables, (i.e. sex and diagnosis of patients) were analysed. The rest period was used as the base line to which each value associated with the non-painful or the painful procedure was compared using an independent t-test. When no significant relationship was detected between the procedures and the measurements, the data were processed through the next step. Statistical significance was analysed using a one-way ANOVA, which is used to compare pain at rest and the two procedures using each scale. The two way ANOVA is used to compare pain during the procedures using different scales. The chi-square test was used to compare the categorical variables. The Wilcoxon signed rank test to assess the difference in effect size in which the proposed scales predict pain scores during painful and non-painful procedures was examined. As for reliability, the weighted kappa test was calculated to detect the magnitude of agreement between two PNs. Relationships between the variables were detected using linear correlation. The significance for the whole statistical analysis was set at $p = 0.05$. The methods of data analysis employed in this study are show in Table 5.2.

In the next section, the results of the data analysis are presented in relation to the null hypotheses. The data were collected and then processed in response to the analysis to address the problems listed in Table 5.2.

Table 5.2 Summary of the methods used to analyse the null hypotheses

<i>Study null hypothesis</i>	<i>Analysis Methods</i>
H ₁ : There is no relationship between the sets of items in the BPS.	Cronbach's α Spearman's correlations
H ₂ : There is no relationship between the sets of items in the CPOT.	Cronbach's α Spearman's correlations
H ₃ : The agreement is no greater than 0.4 between two independent raters using the BPS.	Cohen's Kappa Spearman's correlations
H ₄ : The agreement is no greater than 0.4 between two independent raters using the CPOT.	Cohen's Kappa Spearman's correlations
H ₅ : The agreement is no greater than 0.4 between two independent raters using the FPRS.	Cohen's Kappa Spearman's correlations
H ₆ : There is no correlation between the increase in pain scores when using the FPRS and BPS on the same patient and at the same time.	Pearson correlation

Table 5.2 Summary of the methods used to analyse the null hypotheses (Continued)

<i>Study null hypothesis</i>	<i>Analysis Methods</i>
H ₇ : There is no correlation between the increase in pain scores when using the FPRS and CPOT on the same patient and at the same time.	Pearson correlation
H ₈ : There are no differences between pain scores using the BPS when patients undergo the painful procedure in comparison to the non-painful procedure.	ANOVA
H ₉ : There are no differences between pain scores using the CPOT when patients undergo the painful procedure in comparison with the non-painful procedure.	ANOVA
H ₁₀ : There are no differences between pain scores using the FPRS when patients undergo the painful procedure in comparison with the non-painful procedure.	ANOVA
H ₁₁ : There is no association between the non-painful procedure's responsiveness and the painful procedure's responsiveness scores when using the BPS.	Wilcoxon signed rank test
H ₁₂ : There is no association between the non-painful procedure's responsiveness and the painful procedure's responsiveness scores when using the CPOT.	Wilcoxon signed rank test
H ₁₃ : There is no association between the non-painful procedure's responsiveness and the painful procedure's responsiveness scores when using the FPRS.	Wilcoxon signed rank test

5.4 Results

The goal of the research was to develop a knowledge base and validate the Chinese versions of the BPS, CPOT, and FPRS, among NVCPs by Chinese-speaking nurses. The findings presented in this section demonstrate the merging of theory and practice. First, Table 5.2 summarises the results—explaining exactly what is going to be tested and how. Then, the null hypotheses are discussed in the same order as in the methods and in the above table, describing what has been done and explaining the extent to which the results verify or refute the tests (Table 5.3).

The test of the null hypotheses consists of examining the reliability and validity of the three pain scales in the NVCPs in the study groups as Group V- validity testing and Group R- reliability testing. The NVCPs, totalling 308 homogeneous patients, were from 8 ICUs in 5 hospitals and randomly divided into two main groups (Group V, n=169, Group R, n=68, Lost to follow up, n=81). Group R comprised a total of 1632 independent observations prior to and during the painful and non-painful procedures using the three pain scales by one pair of PNs on 68 NVCPs in the ICU. The responsiveness of each of the three scales was tested using Group V and comprised 676 observations prior to and during the painful and non-painful procedures using each of the three pain scales by one PN on 169 NVCPs in the ICU. 168 assessments were obtained in 42 adults using the BPS as group A; 260 observations were gathered from 65 adults by using the CPOT as group B; and 248 evaluations were obtained from 62 patients by using the FPRS as group C.

Table 5.3 Summary of results from the null hypotheses testing

Null hypothesis	Analysis Methods	Significance	Correlation coefficient	Results
H ₁	Cronbach's α	-	0.700	Rejected
	Spearman's correlations		0.73~0.83	Rejected
H ₂	Cronbach's α	-	0.821	Rejected
	Spearman's correlations		0.411~0.705	Rejected
H ₃	Cohen's Kappa	-	0.73~1.00	Rejected
	Spearman's correlations		0.826~0.976	Rejected
H ₄	Cohen's Kappa	-	0.80~1.00	Rejected
	Spearman's correlations		0.903~0.984	Rejected
H ₅	Cohen's Kappa		0.37~0.54	Rejected/
	Spearman's correlations		0.775~0.819	accepted at painful; procedure Rejected
H ₆	Pearson correlation		0.471~0.664	Rejected
				Rejected
H ₇	Pearson correlation		0.580~0.661	Rejected Rejected
H ₈	ANOVA	<0.05	-	Rejected
H ₉	ANOVA	<0.05	-	Rejected
H ₁₀	ANOVA	<0.05	-	Rejected
H ₁₁	Wilcoxon signed rank test	<0.001	-	Rejected
H ₁₂	Wilcoxon signed rank test	<0.001	-	Rejected
H ₁₃ :	Wilcoxon signed rank test	<0.001	-	Rejected

Selection bias concerns how the study participants are assigned to comparison groups in a study (Creswell & Plano Clark 2010). Characteristics that might influence the outcomes do not systematically favour the treatment or control group. If more participants leave one of the groups, the results could be due to differences between the characteristics of the groups at the post-test that did not exist at the pre-test. Therefore, it is necessary to analyse characteristic data within group or between groups first. Prior to reporting the statistical results, each section provides the characteristics of the NVCPs in the study groups, including physiological data, pathology, medication and their effect on pain level in patients.

5.4.1 Reliability study

5.4.1.1 Physiological data of Group R

The NVCPs of Group R ($n = 44$, 65%) were male, with a mean age of 62 years ($SD = 15.1$), ranging from 25 to 87 years. All patients had undergone a surgical procedure before receiving the SICU management. In terms of the duration of endotracheal tube placement, these patients had an average of 115 hours, with a standard deviation of 103 hours. The large standard deviation represents the duration of endotracheal intubation. This includes a wide range of values (14 to 430). The distribution of disease severity across this group was estimated by classifying all patients with APACHE II. Patients had an average score of 17 and the same value of the mode and median at 18, all with 25% mortality (Herdman et al. 1997). The patients' vital signs were stable so it is reasonable to assume that these data are distributed normally (Table 5.4).

Table 5.4 Physiological data of Group R in this study (n=68).

Variables	Frequency (%)/ Mean (SD)	Range
Sex		
<i>Male</i>	44 (65%)	
<i>Female</i>	24 (35%)	
Age	61.6 (15.1)	25-87
Endotracheal time (ETT) (hour)	115.1 (102.6)	14-430
Body temperature (BT)	37.1 (0.6)	36.0-38.5
Heart rate (HR) (beats/min)	87.5 (11.7)	68-120
Respiratory rate (RR) (breaths/min)	15.7 (2.8)	6-39
Systolic blood pressure (SBP) (mmHg)	123.4 (17.7)	91-171
Diastolic blood pressure (DBP) (mmHg)	66.3 (11.8)	47-96
Mean arterial pressure (MAP) (mmHg)	85.3 (11.6)	63-120
Apache II *	17.0 (6.2)	5-33

**Apache II- Acute Physiology and Chronic Health Evaluation (an integer score from 0 to 71 is computed based on several measurements; higher scores correspond to more severe disease and a higher risk of death)*

5.4.1.2 Pathology conditions of Group R

The majority of NVCPs (n=44, 65%) were male in this reliability study. Their diagnosis varied greatly, from pneumonia to multi-trauma. “Diseases of the circulatory system” (n=31, 45.6%) was coded on the majority of cases in Group R for the reliability study. Only one patient (1.5%) had an injury and another suffered from a disease of the blood and blood-forming organs. The majority of NVCPs (n=46, 68%) were alert and calm, scoring zero. Only one NVCP (n=1, 1.5%) scored two and another (n=1, 1.5%) was under deep sedation on the RASS. The NVCPs’ state of consciousness scores showed that 6 NVCPs had minor

unconsciousness and GCS 10E. Most NVCPs (n=50, 74%) scored between 7E and 9E and 12 NVCPs scored below 6E (Table 5.5).

Table 5.5 Pathology Conditions of the Group R (n=68).

Variables	Frequency (percentage)
Diagnosis	
Certain infectious and parasitic diseases	0 (0%)
Neoplasms	18 (26.5%)
Diseases of the blood and blood-forming organs	1 (1.5%)
Endocrine, nutritional & metabolic diseases	0 (0%)
Diseases of the nervous system	2 (2.9%)
Diseases of the circulatory system	31 (45.6%)
Diseases of the respiratory system	2 (2.9%)
Diseases of the digestive system	7 (10.3%)
Diseases of the skin and subcutaneous tissue	2 (2.9%)
Diseases of the musculoskeletal system	2 (2.9%)
Diseases of the genitourinary system	2 (2.9%)
Injury, poisoning	1 (1.5%)
RASS*	
-4	1(1.5%)
-3	1(1.5%)
-2	3 (4.4%)
-1	7 (10.3%)
0	46 (67.6%)
1	9 (13.2%)
2	1 (1.5%)
GCS**	
4E	0 (0%)
5E	1 (1.5%)
6E	11 (16.2%)
7E	8 (11.8%)
8E	19 (27.9%)
9E	23 (33.8%)
10E	6 (8.8%)

* **RASS:** *RASS-Richmond Agitation-Sedation Scale (1= Restless, 0=Alert and calm, -1=Drowsy, -2=Light sedation, -3=Moderate sedation, -4=Deep sedation, -5=Unarousable)

**GCS: Glasgow Coma Scale (Severe, with GCS ≤ 8, Moderate, GCS 9–12, Minor, GCS ≥ 13)

5.4.1.3 Administration of sedative and analgesic medications of Group R

The NVCPs were receiving continuous infusions of analgesic and sedative medication as part of the standardised ICU protocols (Table 5.6). The decision to administer a bolus was based upon a nurse's clinical judgment and perception of the patient's pain under the general supervision of a physician. A high proportion of NVCPs (n=27, 40%) were receiving a fentanyl infusion (337.54µg/h) which is accounted for in this research. In terms of sedative medication, several NVCPs were managed with benzodiazepines (n=7, 10%, 12.70mg/h) and propofol (n=17, 40%, 97.08 mg/h) infusions. Among the procedures for which the patients were assessed, those patients receiving an analgesic or sedation medication still received that medication infusion, as required.

Table 5.6 Administration of analgesic and sedative regimen of NVCPs (n=68)

	Propofol	Benzodiazepines	Fentanyl
Frequency	17 (25%)	7 (10%)	27 (40%)
Mean	97.1 mg/h	12.70 mg/h	337.5µg/h
Standard Deviation	88.9 mg/h	22.65 mg/h	387.6µg/h
Median	92.1 mg/h	2.87 mg/h	130.8µg/h

Abbreviation: mg = milligram; µg = microgram; h = hour

ICU continuous sedation/analgesia for intubated mechanically ventilated patients

A consistent scale or measurement instrument will be expected to show the same scores on two separate occasions using the same sample. Internal consistency and equivalence will be discussed in the following analysis.

5.4.1.4 Internal consistency

The results of the pain assessment during the painful procedure are presented in Table 5.7. This is used to explore the distribution of scores and the internal consistency to indicate which items of the BPS and CPOT may be interrelated. The BPS has a total of three subscales with four items, each of which comprises the complete scale. The summated scores can range from a low of 3 to a high of 12. The mean of the three individual items of the BPS ranged from 1.59 to 2.32 for each item, with SD ($\pm 0.47 \sim \pm 0.60$). The CPOT consists of four sub-scales with three items each. The scoring for each sub-scale ranges from zero (no response) to two (full response). The summated scores can range from a low of 0 to a high of 8. The mean of the four individual items of the CPOT ranged from 0.91 to 1.63 for each item, with SD ($\pm 0.52 \sim \pm 0.69$).

The internal consistency and reliability of the items in the BPS and CPOT were assessed using the Cronbach α . This reliability coefficient normally ranges from 0 to 1. George and Mallery (2003) suggest interpreting the Cronbach α as follows: > 0.9 – Excellent, > 0.8 – Good, > 0.7 – Acceptable, > 0.6 – Questionable, > 0.5 – Poor, and < 0.5 – Unacceptable (p. 231). The BPS at rest score has a Cronbach's $\alpha = 0.501$, the non-painful procedure has a Cronbach's $\alpha = 0.562$ and the painful procedure a Cronbach's $\alpha = 0.700$ in a total of 68 patients. The consistency is potentially questionable between the items of the BPS when the patients are at rest or receiving the non-painful procedure, as the Cronbach's α indicates. However, the overall Cronbach's $\alpha = 0.700$ for the BPS indicates good internal consistency of the items. The CPOT scale showed a slightly higher internal consistency at rest, with Cronbach's $\alpha = 0.697$, the non-painful procedure showed

a Cronbach's $\alpha=0.733$, and the painful procedure Cronbach's $\alpha=0.821$. These scores strongly suggest that the items exhibit high internal consistency.

The item to total correlations was also used to explore the internal consistency in this reliability study. A small item-correlation provides empirical evidence that this item is failing to measure the same construct measured by the other items included. A correlation value of less than 0.2 or 0.3 indicates that the corresponding item does not correlate very well with the scale overall and thus may be dropped (Wright & Young 1997). The corrected item-total correlations of the subscales ranged from 0.48 to 0.55 for the total BPS. The scale's Cronbach's α would be 0.654 if item I, "facial expression", were removed from the scale (Table 5.10). This value is then compared with the Cronbach's α coefficient value of the total scale to test the difference after the item has been deleted. Based on the conventions of statistical analysis for the task value item I (facial expression), the Cronbach's α when item I is deleted will reduce the Cronbach's α from 0.700 to 0.654 for the entire scale. As the alpha coefficient drops with the removal of item I, this suggests that item I is useful and contributes to the overall reliability of the BPS. Based on the analysis of items II and III, "Upper limbs movement" and "Compliance with mechanical ventilation" respectively, both items are designed to measure the task value and contribute to the overall reliability of the BPS. The results provide evidence that the removal of any of the task value items will not improve the measurement of the construct.

The mean of the four items of the CPOT has a minimum value of 0.912 and a maximum value of 1.632, with a variance of 0.088. Examining the task values of

the CPOT, the correlation for item I (Facial expression) is $r=0.550$, item II (Body movement) $r=0.658$, item III (Muscle tension) $r=0.769$ and item IV (Compliance with mechanical ventilation) $r=0.631$. These r values show a strong correlation between the scores for item I “Facial expression” and the combined scores for the other three items comprising the CPOT. To examine the reliability of the construct further, the effect of deleting any of the items in the CPOT and the Cronbach’s α was calculated. Deleting any item reduced the overall reliability (Cronbach’s α) of the scale. The removal of item I (Facial expression) resulted in a Cronbach’s α of 0.815. The removal of item II decreased the Cronbach’s α with a resultant value of 0.769. The deletion of items III (Muscle tension) and IV (Compliance with mechanical ventilation) exhibited a similar reduction in the Cronbach’s α of 0.718 and 0.792 respectively. These results unequivocally suggest that these four items are necessary in order to measure the construct accurately.

The one-way ANOVA test examines the variance between the items within the same scale as well as the variance between the items of another scale measuring the same construct. In this study, the variances of interest are the items of the CPOT both within the scale as well as the variance within and between that of the BPS. The F value of the ANOVA one way test when it is close to or equal to one suggests that there is little to no variance within and between the means of the items. The ANOVA and the F value of the BPS were [$F(2, 134) = 62.98, p < 0.001$] for $n = 68$. The CPOT presented comparable results, with [$F(3, 201) = 35.58, p < 0.001$] and $n = 68$. For both scales, the one way ANOVA with the examination

focusing on the variance between and within items as well as those between and within the scales are statistically significant.

Table 5.7 Distribution of the scores and reliability coefficients of the BPS and CPOT in the representative sample (n=68)

	Observed Range	Mean \pm SD	Item- total correlation	Cronbach's α if item deleted	Cronbach's α for total scale
BPS	3-12	5.78 \pm 1.22			0.700
Facial expression	1-4	2.32 \pm 0.47	0.480	0.654	
Upper limbs movement	1-4	1.87 \pm 0.45	0.549	0.581	
Compliance with mechanical ventilation	1-4	1.59 \pm 0.60	0.551	0.584	
CPOT	0-8	4.96 \pm 1.86			0.821
Facial expression	0-2	1.63 \pm 0.52	0.550	0.815	
Body movement	0-2	1.22 \pm 0.54	0.658	0.769	
Muscle tension	0-2	1.19 \pm 0.55	0.769	0.718	
Compliance with mechanical ventilation	0-2	0.91 \pm 0.69	0.631	0.792	

The pain scores recorded by the two assessment tools are ordinal scales. The Spearman's Rank Order correlation was run to determine the relationship between the pain scores for each item and the items of both the BPS and CPOT in Group R (n=68). The scores evaluated for this aspect of the analysis were based on the data collected from one PN while evaluating an NVCP during the painful procedure using the CPOT or BPS.

A Spearman's coefficient of +1 is numerical proof that a perfect association exists between the ranked variables (item pain scores). An average inter-item correlation of $r_s=0.78$ with the individual correlations ranging from 0.73 to 0.83 suggests a strong association between the BPS items. The Spearman's correlations between "facial expression" and "upper limbs movement" is $r_s=0.746$ ($p<0.01$). For "facial expression" and "compliance with mechanical ventilation", the correlation is $r_s=0.729$ ($p<0.01$). The "upper limbs movement" and "compliance with mechanical ventilation" shows $r_s=0.827$ ($p<0.01$). This means that the research null hypothesis that a strong relationship exists between each item must be rejected. The relationship is in the predicted direction (positive) and can be generalised to the population ($p<0.01$, 2-tailed). The Spearman coefficient for the CPOT relationship between "facial expression" and "body movement" is 0.537 and statistically significant at $p<0.01$, 2-tailed. A statistically significant relationship exists between the remaining items, as shown in Table 5.8. As the r value for each variable (item of interest) of the CPOT increases, the variable of comparison (item) of the CPOT also increases, as predicted. However, is this a strong association? At $r_s=0.411$, the coefficient of the relationship between "facial expression" and "compliance with mechanical ventilation" is not "perfect" (+1). A Spearman's coefficient of zero would suggest that there is no association between the items, however, $r_s=0.411$ is not zero. The coefficient of the relationship between "muscle tension" and "compliance with mechanical ventilation" is $r_s=0.705$, $p<0.01$, suggesting that the relationship between the two items is strong.

It is impossible to calculate reliability exactly. Instead, reliability is estimated and remains an imperfect endeavour. In the following section, inter-rater reliability was further established using percent agreement procedures.

Table 5.8 Inter-item correlations of BPS and CPOT in the Group R (n=68)

Item indicators	Facial expression	Upper limbs / Body movement	Muscle tension	Compliance with mechanical ventilation
BPS				
Facial expression	1.000			
Upper limbs movement	0.746**	1.000		
Compliance with mechanical ventilation	0.726**	0.827**		1.000
CPOT				
Facial expression	1.000			
Body movement	0.537**	1.000		
Muscle tension	0.466**	0.654**	1.000	
Compliance with mechanical ventilation	0.411**	0.444**	0.705**	1.000

**** Correlation is significant at the 0.01 level (2-tailed)**

5.4.1.5 Inter-rater consistency

Consistency reliability is assessed by having two independent PNs score the pain scales on the same NVCP at the same time. The Spearman correlation coefficients will indicate if the test scores are strongly associated. Prior to the consistence exam, the independent sample t test will indicate if the scores of the second PN are the same (versus systematically higher or lower) as those of the first PN. For each scale, 204 observations for testing inter-rater reliability were rated by two

PNs at rest for the non-painful and painful procedures (Table 5.9). An independent sample t test was used to assess whether difference existed between the BPS, CPOT and FPRS with the working assumption that the pain scores are ordinal in nature.

5.4.1.5.1 The BPS

A non-significant mean difference between the total BPS scores by PN 1 [$t(134) = -0.220, p > 0.05$] and PN 2 [$t(134) = -0.101, p > 0.05$] suggests low to no variation between the PNs, as both values are close to zero. The Spearman correlations ($r_s = 0.826 \sim 0.976, p < 0.001$) are extremely high between the two PNs which indicates consistent inter-rater reliability.

The standard deviation of the mean pain scores between the two PNs [PN 1 (3.13 ± 0.54), PN 2 (3.15 ± 0.55), $r_s = 0.976$] was extremely low, with a high Spearman's coefficient for the NVCP when scored at rest. The same scale (BPS) and PNs 1 and 2, scoring the same NVCP at the same time during the non-painful procedure, scored a standard mean deviation as follows (4.03 ± 0.91), (4.04 ± 0.83) and $r_s = 0.936$. Similarly, for the painful procedure, the standard deviation between the pain scores and between raters was calculated as PN1 (5.78 ± 1.22), PN2 (5.88 ± 1.20) and $r_s = 0.826$. The Spearman's coefficient slightly decreases when the NVCP is stimulated, whether the procedure is painful or non-painful, although this remains not significant.

5.4.1.5.2 The CPOT

The examination of the CPOT standard mean deviation of pain scores between raters reveals PN1 (0.49 ± 0.97) and PN2 (0.49 ± 0.93), with $r_s = 0.984$ for the NVCP at rest. The scores between the PNs for the same NVCP during the non-painful procedure were as follows: PN1 (4.03 ± 0.91) and PN2 (4.04 ± 0.83), with $r_s = 0.936$. Similarly comparable results were obtained for the painful procedure with PN 1 (5.78 ± 1.22) and PN 2 (5.88 ± 1.20) with $r_s = 0.826$. The analysis of the CPOT data revealed no statistical differences between the mean of the pain scores for PN 1 and PN 2 for the at rest, painful and non-painful procedures. The results for the inter-rater reliability for the CPOT are [$t(134) = 0.000$, $p > 0.05$] and [$t(134) = 0.356$, $p > 0.05$], respectively. These results suggest that strong reliability exists.

5.4.1.5.3 The FPRS

The inter-rater reliability of the FPRS showed non-significant differences between the standard median of deviation of the pain scores (Mean= 2.13 ± 0.83) as assessed by both PNs (Mean= 2.03 , SD= ± 0.59) at rest. Similar results were obtained for both the painful and non-painful procedures. The non-painful procedure resulted in PN1 (3.54 ± 1.55) and PN2 (3.22 ± 1.10), with $r_s = 0.819$. The painful procedure showed a slightly greater deviation, with PN1 (5.76 ± 1.51) and PN2 (6.04 ± 1.49), with $r_s = 0.775$. Using the data set collected during the FPRS investigation, the independent t test revealed [$t(134) = 0.832$, $p = 0.407$]. The agreement between the PNs remained moderately high for the NVCP at rest and the r_s increases for the non-painful procedure ($r_s = 0.819$), then

decreases for the painful procedure ($r_s=0.775$). There were no statistically significant differences between the two means for the pain scores assessed in patients for either the non-painful procedure [$t(134)=1.402$, $p>0.05$] or the painful procedure [$t(134)=-1.087$, $p>0.05$]. Both show a strong association between their ratings across the non-painful procedure ($r_s=0.819$, $p<0.001$) and the painful procedure ($r_s=0.775$, $p<0.001$). Among the 68 paired assessments, there exists a high degree of correlation between the BPS and CPOT as scored by the two PNs on the same NVCP.

Table 5.9 Standard deviation of the mean of the pain scores as assessed by two raters for the BPS, CPOT and FPRS (n=68)

	PN1	PN2	r_s
BPS			
Rest	3.13±0.54	3.15±0.55	0.976*
Non-painful procedure	4.03±0.91	4.04±0.83	0.936*
Painful procedure	5.78±1.22	5.88±1.20	0.826*
CPOT			
Rest	0.49±0.97	0.49±0.93	0.984*
Non-painful procedure	2.00±1.46	2.09±1.42	0.945*
Painful procedure	4.59±1.94	4.96±1.86	0.903*
FPRS			
Rest	2.13±0.83	2.03±0.59	0.777*
Non-painful procedure	3.54±1.55	3.22±1.10	0.819*
Painful procedure	5.76±1.51	6.04±1.49	0.775*

**Spearman's rank correlation coefficient*

Another important aspect in assessing inter-rater reliability is to determine how well an implementation of measurement works between two PNs on the subscales

of the CPOT and BPS using the weighted Cohen's Kappa. Kappa values greater than 0.40 are considered moderate based on the standard benchmarks employed in the field (Landis and Koch 1977).

The FPRS has only the dimension of facial expression for rating pain. This section presents Cohen's kappa (k), where the inter-rater agreements were hypothesised as moderate. The Cohen's kappa coefficient for the FPRS at rest ($k=0.54$), during the painful procedure ($k=0.45$) and during the non-painful procedure ($k=0.37$) were confirmed. The $k=0.37$ for patients during the non-painful procedure indicates a fair agreement between the two PNs. Similarly, for the BPS, the standard deviation around the mean of the pain values rated by the two PNs and the Cohen's kappa showed substantial agreement between the subscales. During the painful procedure, "Facial expression" (0.77) and "Upper limbs movement" (0.73) showed strong reliability between the PNs. The Cohen's Kappa scored extremely high, at $k=0.80$, or almost perfect agreement for the BPS subscales when the NVCPs were at rest or undergoing non-painful and painful regimes. The subscale "Compliance with mechanical ventilation" scored $k= 1.00$ at rest and during the non-painful procedure, with $k=0.92$ for the painful procedure. Similar results for the CPOT were obtained with only a slight variation. Of particular interest to the CPOT is the subscale "Muscle tension", with the Cohen's Kappa ranging from 0.65 to 1.00. The CPOT scoring for the "muscle tension" subscale revealed a Cohen's Kappa of 1.00, which is perfect agreement. The non-painful procedure revealed a $k= 0.90$ and the painful procedure resulted in $k=0.65$. Notably, the item "Muscle tension", which is unique to the CPOT, showed almost perfect agreement between the two PNs with the NVCP at rest (1.00). The non-

painful procedure scored $k=0.90$, with only a moderate agreement during the painful procedure of $k=0.65$. The distribution of the BPS, CPOT and FPRS subscale scores and the results of the weighted Cohen's Kappa for the ratings of equivalence can be found in Table 5.10.

5.4.1.6 Summary

This section explored the analysis of the research focusing on the consistency and reliability of the BPS, CPOT, and FPRS scales. The analysis aims to confirm that these scales are capable of assessing what they are designed to measure. Given the complexity of the nature of the experience to be measured, multiple aspects must be examined simultaneously. These aspects were then further examined for internal consistency and inter-rater reliability of the three scales. Based on acceptable reliability results, the three scales were investigated for validity.

Table 5.10 Distribution of subscale scores and Cohen's Kappa coefficients for the BPS, CPOT and FPRS in the representative sample (n=68)

	Facial expression			Upper limb movements			Muscle tension			Compliance with mechanical ventilation		
	Mean±SD			Mean±SD			Mean±SD			Mean±SD		
	PN 1	PN 2	<i>k</i>	PN 1	PN 2	<i>k</i>	PN 1	PN 2	<i>k</i>	PN 1	PN 2	<i>k</i>
BPS												
Rest	1.18±0.3	1.19±0.4	0.95	1.00±0.0	1.00±0.0	1.00	-	-	-	1.00±0.0	1.00±0.0	1.00
Non-painful procedure	1.75±0.5	1.78±0.5	0.80	1.26±0.4	1.25±0.4	0.96	-	-	-	1.03±0.2	1.03±0.2	1.00
Painful procedure	2.32±0.4	2.32±0.5	0.77	1.87±0.5	1.93±0.4	0.73	-	-	-	1.60±0.6	1.65±0.6	0.92
CPOT												
Rest	0.31±0.5	0.29±0.4	0.89	0.04±0.2	0.06±0.2	0.85	0.07±0.2	0.07±0.3	1.00	0.01±0.1	0.01±0.1	1.00
Non-painful procedure	1.00±0.5	1.04±0.5	0.82	0.53±0.6	0.56±0.6	0.89	0.34±0.5	0.35±0.5	0.90	0.13±0.3	0.13±0.3	1.00
Painful procedure	1.57±0.5	1.63±0.5	0.82	1.15±0.6	1.22±0.5	0.80	1.04±0.6	1.19±0.6	0.65	0.81±0.7	0.91±0.7	0.83
FPRS												
Rest	2.13±0.8	2.03±0.6	0.54	-	-	-	-	-	-	-	-	-
Non Painful procedure	3.54±1.5	3.22±1.1	0.37	-	-	-	-	-	-	-	-	-
Painful procedure	5.76±1.5	6.04±1.5	0.45	-	-	-	-	-	-	-	-	-

5.4.2 Validity study

Construct validity is the approximate truth of the conclusion that the operationalisation accurately reflects its construct. However, since the construct that the researcher is attempting to measure is latent, construct validity is unattainable. For the objective of psychometric testing, content validity and criterion-related validity were performed in this study.

Content validity considers whether a scale has included all of the relevant and excluded all of the irrelevant issues in terms of its composition (Bannigan & Watson 2009). The importance of the content validity is reflected in the reliability and validity of the scales post translation from English to Chinese and subsequent use for NVCPs. To explore the quality of the scales for pain assessment, criterion-related validity, concurrent validity and discriminant validity are examined.

The method of validation of the three pain scales is to assess accurately and relate the pain scale scores to the NVCPs' experience of pain while undergoing medical treatment. Currently, no pain scales have been validated for quantifying pain in ICU NVCPs. This study evaluated the validity of the three pain scales by

gathering indirect arguments assessing whether or not the scales accurately measure levels of pain. This study applied comparisons using the FPRS as a standard criterion as it is one of the most common pain scales used in health care, to understand where there may be a statistical association between the proposed measurements (the BPS and CPOT) and the FPRS. Data were collected from Group R (n=68) and the results compared to the test level of agreement, where the FPRS is considered the standard.

An indirect argument for testing the validity of the three scales for scoring pain, is to evaluate two different care procedures that are suspected to be non-painful or painful. The focus is on pain score assessment in relation to Group V population sample type (Group A=BPS, Group B=CPOT, Group C=FPRS). This is necessary in order to substantiate further analysis. Examination of the discriminant validity is essential as, currently, the FPRS remains validated for use with children and dementia patients only.

This section includes in advance of the three main features of Group V (n=169): physiological data, pathology and medication. The possible effects of these

characteristics are quantitatively assessed for potential influence on the painful and non-painful procedures.

5.4.2.1 Physiological data

Group V consisted of three groups, each representing the testing of one pain scale. Within Group V is group A (n=42, BPS), group B (n=65, CPOT) and group C (n=62, FPRS). Group A's average age was 66.8 years old (SD=15.2), group B's was 67.0 years old (SD=14.9) and group C's was 70.3 years old (SD=17.2). Despite the age range of 28 to 95 years old, there were no significant differences in age between the three groups, with $F(2, 166)=0.86$, $p=0.424$. Similarly, patients in the three groups had an equal mean duration of mechanical ventilation of 129 hours with a standard deviation of 130 hours, $F(2, 166)=0.00$, $p=1.000$. The NVCPs' pathology, medical treatment and haemodynamic status (MAP, SBP, DBP, HR, RR, and BT) did not differ significantly across the three groups, with $p<0.05$ (Table 5.11).

Table 5.11 Characteristics of the Group V in this study.

	BPS, n= 42	CPOT, n= 65	FPRS, n= 62	F	p (between groups)
Sex				0.18	0.915
<i>Male</i>	30 (71.4%)	45 (69.2%)	45 (72.6%)		
<i>Female</i>	12 (28.6%)	20 (30.8%)	17 (27.4%)		
Age	66.8 (15.2)	67.0 (14.9)	70.3 (17.2)	0.86	0.424
ETT (h)	129 (129)	129 (130)	130 (140)	0.00	1.000
BT (centigrade)	87.4 (12.3)	85.9 (13.7)	87.8 (12.3)	0.201	0.818
HR (beats/min)	91.2 (14.5)	90.8 (17.4)	92.6 (13.6)	0.686	0.505
RR (breaths/min)	66.3 (11.1)	65.8 (13.1)	68.1 (11.7)	0.611	0.544
SBP (mmHg)	91.7 (15.5)	87.9 (16.6)	89.7 (14.3)	0.763	0.468
DBP (mmHg)	17.5 (5.9)	17.8 (5.5)	17.0 (4.1)	0.384	0.681
MAP (mmHg)	36.9 (0.5)	36.7 (0.7)	36.8 (0.7)	1.748	0.177
Apache II	20.6 (7)	20.8 (8)	20.7 (8)	0.10	0.990
Sedation dose(mg/h)	31.57 (41.5)	43.0 (63.9)	48.2 (52.1)	0.405	0.669
Analgesia dose (µg/h)	310.6 (403)	402.0 (502)	408.7 (449)	0.336	0.716

One-way ANOVA test: $p < 0.005$

Abbreviation: ETT = endotracheal time; BT = body temperature; HR = heart rate; RR = respiration rate; SBP = systolic blood pressure; DBP = diastolic blood pressure; MAP = mean arterial pressure; mmHg = millimeter of mercury (a manometric unit of pressure); h = hour; mg = milligram; µg = microgram

Apache II- Acute Physiology and Chronic Health Evaluation (an integer score from 0 to 71 is computed based on several measurements; higher scores correspond to more severe disease and a higher risk of death)

5.4.2.2 Pathology

A One-way ANOVA analysis was performed to examine the differences with categorical variables (Field 2009). This analysis included: diagnosis, severity of disease, and the sedative and consciousness levels of NVCPs in the three groups (group A (n=42, BPS), group B (n=65, CPOT) and group C (n=62, FPRS) (as shown in Table 5.12). The test failed to indicate a significant difference between those categorical variables at an alpha level of 0.05 and was thus adopted for this and all subsequent statistical tests.

The gender distribution in Group V was primarily male (males n=120, females n=49). The principal diagnosis at ICU admission was “Diseases of the respiratory system” for all sub-groups of group V. The distribution of “Diseases of the respiratory system” was BPS (n=14, 33.3%), CPOT (n=22, 33.8%) and FPRS (n=21, 33.9%). “Diseases of the circulatory system” had a slightly altered distribution across the three sub-groups, with BPS (n=9, 21.4%), CPOT (n=14, 21.5%) and FPRS (n=7, 11.3%) Diseases described as “Neoplasms” were the third most common diagnosis at time of admission and were distributed accordingly: BPS (n=7, 16.7%), CPOT (n=11, 16.9%) and

FPRS (n=14, 22.6%). The three groups showed no difference in terms of distribution of the disease or demographic data [$F(20, n=169) = 15.28, p=0.760$]. Severity of the disease across the three sub-groups showed a 29.5% mortality, with Apache II scores of 15-19 (BPS n=13, 31%, CPOT n=20, 31%, FPRS n=14, 23%). There was no difference in distribution for severity of disease across the three sub-groups [$F(14, n=169) = 16.23, p=0.299$].

Table 5.12 Pathology data of Group V

	Validity groups, n=169				<i>P</i> (between groups)
	BPS, n = 42	CPOT, n= 65	FPRS, n= 62	F	
Diagnosis				15.28	0.760
Certain infectious and parasitic diseases	4 (9.5%)	5 (7.7%)	9 (14.5%)		
Neoplasms	7 (16.7%)	11 (16.9%)	14 (22.6%)		
Diseases of the blood and blood-forming organs	1 (2.4%)	1 (1.5%)	0 (0%)		
Endocrine, nutritional & metabolic diseases	1 (2.4%)	1 (1.5%)	0 (0%)		
Diseases of the nervous system	1 (2.4%)	0 (0%)	0 (0%)		
Diseases of the circulatory system	9 (21.4%)	14 (21.5%)	7 (11.3%)		
Diseases of the respiratory system	14 (33.3%)	22 (33.8%)	21 (33.9%)		
Diseases of the digestive system	3 (7.1%)	7 (10.8%)	6 (9.7%)		
Diseases of the skin & subcutaneous tissue	0 (0%)	0 (0%)	1 (1.6%)		
Diseases of the musculoskeletal system	1 (2.4%)	2 (3.1%)	4 (6.5%)		
Diseases of the genitourinary system	1 (2.4%)	2 (3.1%)	0 (0%)		
Injury, poisoning	0 (0%)	0 (0%)	0 (0%)		

One-way Analysis of Variance (ANOVA) test, $p < 0.05$

Table 5.12 Pathology data of Group V (Continued)

	Validity groups, n=169			F	p (between groups)
	BPS, n = 42	CPOT, n= 65	FPRS, n= 62		
Apache II				16.23	0.299
0-4	0 (0%)	0 (0%)	3 (4.8%)		
5-9	3 (7.1%)	2 (3.1%)	5 (8.1%)		
10-14	5 (11.9%)	9 (13.8%)	7 (11.3%)		
15-19	13 (31.0%)	20 (30.8%)	14 (22.6%)		
20-24	4 (9.5%)	15 (23.1%)	15 (24.1%)		
25-29	13 (31.0%)	11 (16.9%)	10 (16.1%)		
30-34	4 (9.5%)	5 (7.7%)	6 (9.7%)		
>35	0 (0%)	3 (4.6%)	2 (3.2%)		
RASS*				11.87	0.294
-4	0 (0%)	0 (0%)	0 (0%)		
-3	3 (7.1%)	3 (4.6%)	0 (0.0%)		
-2	8 (19.0%)	5 (7.7%)	10 (18.1%)		
-1	8 (19.0%)	9 (13.8%)	12 (19.4%)		
0	20 (47.6%)	38 (58.5%)	31 (50.0%)		
1	2 (4.8%)	9 (13.8%)	9 (14.5%)		
2	1 (2.4%)	1 (1.5%)	0 (0.0%)		
GCS**				11.92	0.452
4E	1 (2.4%)	1 (1.5%)	0 (0%)		
5E	1 (2.4%)	5 (7.7%)	4 (6.5%)		
6E	5 (11.9%)	6 (9.2%)	5 (8.1%)		
7E	11 (26.2%)	10 (15.4%)	13 (21.0%)		
8E	15 (35.7%)	20 (30.8%)	20 (32.3%)		
9E	5 (11.9%)	17 (26.2%)	8 (12.9%)		
10E	4 (9.5%)	6 (9.2%)	12 (19.4%)		

One-way Analysis of Variance (ANOVA) test, $p < 0.05$

**RASS-Richmond Agitation-Sedation Scale (1= Restless, 0=Alert and calm, -1=Drowsy, -2=Light sedation, -3=Moderate sedation, -4=Deep sedation, -5=Unarousable); **GCS-Glasgow Coma Scale (Severe, with GCS ≤ 8 , Moderate, GCS 9–12, Minor, GCS ≥ 13)*

To assess the effect of sedation and levels of consciousness on NVCPs, the RASS and GCS scores were analysed. Group B was evaluated using the CPOT and scored slightly higher RASS (0) and GCS (9E) as opposed to group A and group C, who C did not show any anomalies. The differences across the groups were found to be non-significant at $F(10, n=169)=3.52, p=0.17$ and $F(12, n=169)=3.52, p=0.17$.

5.4.2.3 Administration of sedative and analgesic medication

Details of the patients' sedation, analgesia, and anaesthesia administered prior to the procedures were recorded (Table 5.13). The administration of sedation and analgesia is an integral part of ICU practice. Although the use of analgesia and sedation is the foundation of patient comfort in an ICU setting and has a long record of safety, researchers must be aware that cognitive function and coordination may be modestly impaired (Cammarano et al. 1998). Large doses of local anaesthetics may result in central nervous system depression, especially when combined with sedative agents which are also muscle relaxants (Wheeler 1993). This combination may result in the absence of pain behaviour (Cammarano et al. 1998). As such, the research will address the

NVCPs' sedation and consciousness level and examine the effects of various sedative medications and analgesia.

NVCPs receiving Propofol, Benzodiazepines, and Fentanyl presented large standard deviations in each of the validity sub-groups. However, across the three groups, this remained non-significant, as Propofol [$F(2, n=167)=8.99, p=0.174$], Benzodiazepines [$F(2, n=167)=0.87, p=0.649$] and Fentanyl [$F(2, 167)=0.399, p=0.136$].

As the physiological data, pathology, and medication data suggest homogeneity, the pain scores assessed using the BPS, CPOT and FPRS will be analysed in the following section.

Table 5.13 Description of analgesic and sedative regimen of the patients

	Validity groups, n=169				<i>p</i> (between groups)
	BPS, n = 42	CPOT, n= 65	FPRS, n= 62	F	
Propofol				8.99	0.174
Frequency	6	12	2		
Mean*	7.7	28.2	30.0		
Standard Deviation*	16.3	66.5	41.1		
Median*	0.8	0.9	30.0		
Benzodiazepines				0.87	0.649
Frequency	11	15	14		
Mean*	44.4	54.8	50.7		
Standard Deviation*	45.8	61.5	54.2		
Median*	19.2	20.8	49.4		
Fentanyl				3.99	0.136
Frequency	23	26	22		
Mean*	310.6	402.0	408.7		
Standard Deviation*	403.1	502.3	449.5		
Median*	155	155.8	177.7		

One-way Analysis of Variance (ANOVA) test, $p < 0.05$;

**Dose in mg/hour*

5.4.2.4 Concurrent validity

To assess the lack of correlation between the increase in pain scores when using the FPRS, the BPS and CPOT on the same patient at the same time, the concurrent validity was analysed. Concurrent validity comparing correlations between pain scores and between scales' pain scores in Group R (n=68) using at rest, non-painful, and painful procedures was examined. A Pearson's correlation (r) coefficient of 1 implies that a perfect relationship exists between the ranked variables (item pain scores), 0 that no relationship (Cohen et al. 2002). Concurrent validity data on the outcome variables for an NVCP (Group R, n=68) assessed using the BPS and CPOT compared to the FPRS as the research standard scale is presented in Table 5.14. Pearson's correlations of the BPS scores compared to FPRS ranged from 0.471 to 0.664 ($p<0.01$). The CPOT correlations were similar, with 0.580 to 0.661 ($p<0.01$) for severity of pain at rest and during the non-painful and painful procedures. The results suggest that the total BPS scale and the total CPOT scale have moderate positive correlations with the FPRS. The kappa coefficient values for the subscales and the total scale coefficients for both the BPS and CPOT were in the moderate to high range. These findings provide initial support of criterion

validity for the scale's clinical applicability. To enhance the understanding and potential use of the scales, it is necessary to ascertain the discriminant validity.

Table 5.14 Concurrent validity of patient pain scores at rest and during non-painful and painful procedures as measured by the BPS and CPOT compared with FPRS (n=68)

	BPS		CPOT	
	<i>r</i>	Sig.	<i>r</i>	Sig.
FPRS (Research standard)				<i>p</i> <0.001
Baseline correlation (Rest)	0.664**	<i>p</i> <0.001	0.613**	<i>p</i> <0.001
Follow-up correlation 1 (non-painful stimulus)	0.595**	<i>p</i> <0.001	0.580**	<i>p</i> <0.001
Follow-up correlation 2 (Painful stimulus)	0.471**	<i>p</i> <0.001	0.661**	<i>p</i> <0.001

****Correlation is significant at the 0.01level (1-tailed)**

5.4.2.5 Discriminant validity

The distribution of the means of the NVCPs' pain scores using the three scales at rest and during the two procedures shows some discrepancy (Figure 5.3). Assessments of the at rest (baseline) showed a high percentage of nearly no response using the BPS (score of 3) and the CPOT (score of 0), but a mild response using with the FPRS (score of 2.90). By contrast, the non-painful and painful procedures resulted in unmistakable increases for all three scales (Figure 5.3). It is clear from the data that the pain scores increase from the 'at

rest' point in time when no stimulation, either painful or non-painful, is present.

When the NVCP undergoes either procedure, the pain scores markedly

increase. As predicted, the painful procedure shows the highest scores.

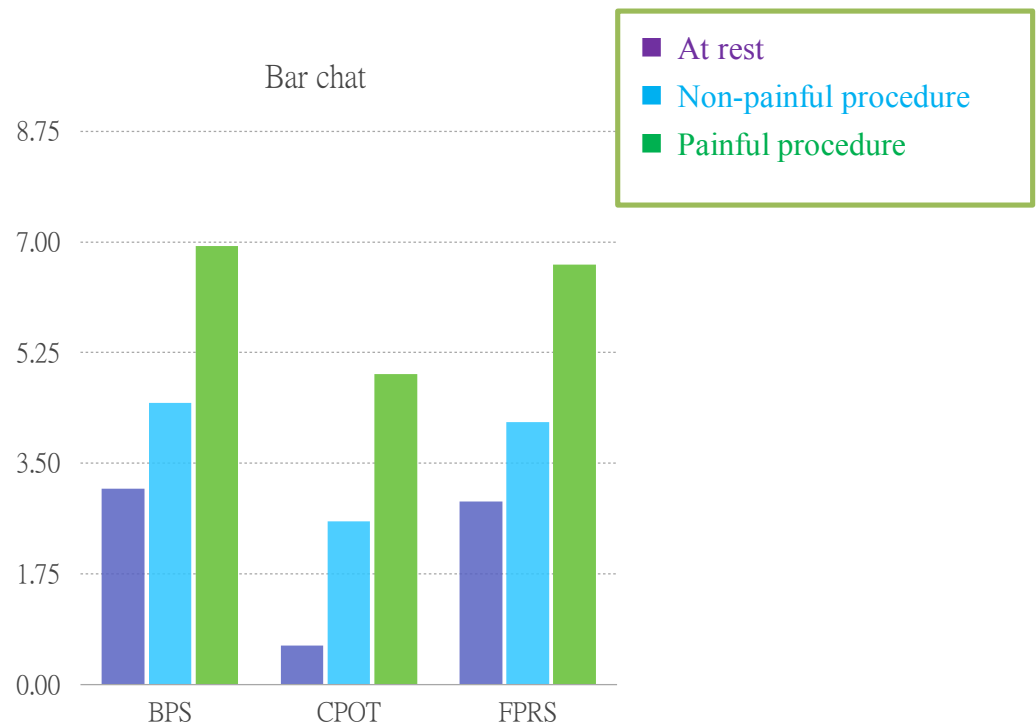


Figure 5.3 Pain intensity bar chart of NVCP assessed using BPS, CPOT and FPRS

Pain scales must be capable of discriminating between NVCPs' levels of experienced pain in a manner that can be predicted. This means that a pain scale with a genuine effect will show a marked contrast in the pattern of scores between the painful or non-painful stimulus. A one way ANOVA test and the difference between the scores 'at rest' and the procedures using the BPS, CPOT, and FRPS can be seen in Table 5.15. The large F ratio and a very small (zero) significant level in each scale indicate a significant effect of procedures on pain scores in all three scales. Significant differences between the pain scores of the BPS corresponding to the three NVCP activities ($F(2, 123)=107.6$, $p<0.001$) suggest predictive reliability . The results of the discriminant validity reject the null hypothesis that the CPOT group's means are similar to those of the BPS and FPRS groups when at rest or undergoing procedures ($F(2, 192)=153.8$, $p<0.001$). Similarly, NVCPs in the FPRS group scored significantly higher for the painful procedure than for the non-painful procedure. However, both procedures scored significantly higher than in the at rest condition: $F(2, 183)=102.6$, $p<0.001$.

Table 5.15 Differences between the mean of BPS, CPOT, and FPRS for all three procedures

Scale	Score range	Rest	Non-painful procedure	Painful procedure	<i>F</i>
BPS (n=42)	3-12	3.10±0.66	4.45±1.15	6.93±1.79	107.66*
CPOT (n=65)	0-8	0.62±0.89	2.58±1.51	4.91±1.67	153.79*
FPRS (n=62)	0-10	2.90±1.36	4.15±1.41	6.64±1.36	102.64*

**The difference between the levels using ANOVA at the $p<0.05$*

The discriminant validity of the BPS, CPOT and FPRS scales was evaluated using Wilcoxon signed rank tests for paired data. This was used to compare scores at rest, during the non-painful and painful procedures using the three scales as assigned to the group V, and then again with the other. P values less than 0.05 were accepted as significant. Descriptive statistics for the difference between each pair of procedures are shown in Table 5.16. The Wilcoxon Signed Ranks Test showed that the BPS can measure a statistically significant change from the at rest condition when compared to the non-painful and painful procedures, The Wilcoxon Signed Ranks Test for the BPS scores between ‘at rest’ and the ‘non-painful’ procedure were ($Z=-5.310$, $p<0.001$) and for the painful procedure ($Z=-5.668$ $p<0.001$). Similarly, the CPOT pain scores increased significantly between the ‘at rest’, painful procedure ($Z=-7.038$, $p<0.001$) and non-painful procedure ($Z=-6.507$, $p<0.001$). A significant increase in pain scores in the FPRS group was also recorded during the painful procedure ($Z=-6.884$, $p<0.001$). The non-painful procedure also showed a marked discomfort level ($Z=-5.982$, $p<0.001$) compared to the at rest condition. The ranks column provides interesting data on the comparison of NVCPs’ pain scores at rest and during the procedures. Not all NVCPs in the three scales’ groups showed an increase or change in pain scores from the at rest condition (CPOT $n=10$, no change; BPS $n=7$, no change and FPRS $n=15$, no change). During the painful procedures, all of the NVCPs in each group showed marked increases in pain score. These results indicate that discriminant validity exists between the three scales when measuring non-painful and painful procedures.

Table 5.16 Changes in the Pain Score from at rest to procedures using the BPS,

CPOT, and FPRS

	Procedures	Signed ranks	N	Mean rank	Sum of ranks	Z value	Sig.
BPS	Pair 1: Rest-Eye care (Non-Painful Procedure)	Negative	0	0.00	0.00		
		Positive	35	18.00	630.00		
		Ties	7				
		Total	42			-5.310	$p<0.001$
	Pair 2: Rest- Endotracheal Suction (Painful Procedure)	Negative	0	0.00	0.00		
		Positive	42	21.50	903.00		
		Ties	0				
		Total	42			-5.668	$p<0.001$
CPO T	Pair 1: Rest-Eye care (Non-painful procedure)	Negative	0	0.00	0.00		
		Positive	55	28.00	1540.00		
		Ties	10				
		Total	65			-6.507	$p<0.001$
	Pair 2: Rest- Endotracheal Suction (Painful Procedure)	Negative	0	0.00	0.00		
		Positive	65	33.00	2145.00		
		Ties	0				
		Total	65			-7.038	$p<0.001$
FPRS	Pair 1: Rest-Eye care (Non-Painful Procedure)	Negative	1	12.5	12.50		
		Positive	46	24.25	1115.50		
		Ties	15				
		Total	62			-5.982	$p<0.001$
	Pair 2: Rest- Endotracheal Suction (Painful Procedure)	Negative	0	0.00	0.00		
		Positive	62	31.50	1953.00		
		Ties	0				
		Total	62			-6.884	$p<0.001$

* *Wilcoxon signed rank tests: $p<0.05$*

5.4.2.6 A comparison of the three pain scales

For the outcome measurements, sensitivity to change is a crucial characteristic.

Responsiveness refers to how sensitive a measure is to indicating change or contrast (Steriner & Norman 2008). In order to assess the sensitivity to change

of each scale, the following analysis assesses the differences between non-painful and painful procedures for each scale with effect size coefficients. All three pain measurement scores were significantly higher during the painful procedure than during the non-painful procedure, with $p < 0.001$.

To assess the association between the non-painful and the painful procedure's responsiveness scores when using the BPS, CPOT and FPRS, the effect size coefficient was examined. Group V (n=169) with one rater (PN) per NVCP, using the Traditional Mandarin version of the BPS and CPOT, FPRS, and clinical information was analysed. NVCPs with an increase in pain severity measure during the painful procedure were considered to undergo "clinical increases". The BPS, CPOT, and FPRS scores all showed statistically significant differences among NVCPs in Group V for the at rest, non-painful procedure and painful procedure (Figure 5.3). The data shown in Tables 5.15 and 5.16 show the mean pain scores of the NVCPs as rated using the three different pain scales. For all three scales, it is apparent that there is an increase in pain or discomfort regardless of the non-painful or painful procedure employed. All three scale scores showed statistically significant differences in their own domains ($p < 0.001$) between rest and during the non-painful or painful procedures. Similarly, all presented a greater increase from rest to painful procedure than from rest to non-painful procedure. Despite the apparent differences between the observed ranges of change in pain, it is impossible to compare directly the magnitude of the difference between the pain scores. Of interest and practical applicability is an assessment of the responsiveness of the scales' ability to detect changes in pain over time

(Wright & Young 1997). Paired mean comparisons (estimated using the Wilcoxon paired test) between baseline (at rest) and the evaluations of patient procedures (non-painful vs. painful) were conducted in group V. Of importance is the magnitude of the difference which was also assessed using the effect size (ES) coefficients. This was calculated by dividing the difference between the mean scores at rest and each procedure by the Standard Deviation (SD) of the mean scores of changes from the non-painful procedure and the at rest condition. An $ES > 0.8$ is considered high, 0.5 moderate, and 0.2 low (Wright & Young 1997).

The changes in all the scores' component summaries (BPS, CPOT and FPRS) among the sub groups of Group V ($n=169$) of NVCPs are shown in Figure 5.3. These scores were significantly greater during the non-painful and painful procedures compared to the at rest condition, and also differed between the two procedures (eye care and endotracheal suction). All subscale scores were also significantly higher during the painful procedure than during the non-painful procedure, with $p < 0.001$ (Table 5.17). The ES coefficients for responsiveness were greater than 0.8 for the three subscale scores of the BPS and the four subscale scores of the CPOT. The ES coefficients of the total scores of the BPS, CPOT, and FPRS were also greater than 0.8 (Table 5.17). The scale with the greatest ES is the BPS ($ES=2.6$), followed by the FPRS ($ES=2.2$), and CPOT ($ES=1.6$). In terms of the subscales, this study found that ESs of the subscale scores in the BPS ($ES=1.6\sim 2.3$) were higher than in the CPOT ($ES=0.9\sim 1.5$). These results show excellent responsiveness and the ability of all three scales to quantify changes in pain in the NVCP's clinical

status. The BPS seems to be potentially the most responsive to changes in pain levels.

Table 5.17 Distribution of pain changes using the BPS, CPOT, and FPRS, and effect size

	No. of effects	Increase scores from rest		<i>Effect Size (ES)</i>
		Non-Painful (Eye care)	Painful Procedure (Endotracheal suction)	
BPS	42			
Facial expression		0.91±0.53	1.74±0.66	1.6*
Upper limbs movement		0.33±0.53	1.14±0.61	1.5*
Compliance with mechanical ventilation		0.09±0.37	0.93±0.78	2.3*
Total		1.33±1.00	3.81±1.69	2.5*
CPOT	65			
Facial expression		0.74±0.64	1.34±0.62	0.9*
Body movement		0.48±0.50	0.94±0.58	0.9*
Muscle tension		0.52±0.50	1.06±0.58	1.1*
Compliance with mechanical ventilation		0.23±0.46	0.94±0.63	1.5*
Total		1.97±1.46	4.29±1.74	1.6*
FPRS	62	1.21±1.04	3.47±1.49	2.2*

**Wilcoxon paired test at $p<0.001$*

5.5 Summary

The above results regarding the validity and reliability of the study help us to identify the potential predictive power of the selected external and internal factors of these three scales. However, all three pain scales have easily identifiable weaknesses. To summarise, the BPS has a lower internal consistency, with a

Cronbach's α of 0.700, compared with the CPOT, at 0.821, although it remains more than acceptable. The FPRS showed a slightly lower relationship in the inter item correlation between two raters' responses than did the BPS and CPOT. The strong findings for both the validity and reliability of the study with the problem apparent in the inter-item correlations prompted closer examination of the perceptions of the PNs, which is part of the qualitative data collection and is discussed further in the next chapter.

The BPS, CPOT, and FPRS are characterised by good distributions for items and total scores. All three scales are acceptable in terms of reliability and validity with regard to assessing pain in NVCPs. The FPRS exhibits a slightly lower inter-rater correlation between the two PNs' responses than that for the BPS or CPOT. In addition, the inter-rater agreement between two raters using the Cohen's kappa coefficient also presented a fair result for the administration of the at rest or non-painful and painful procedures. Considering validity, as explained by the Wilcoxon signed-rank test (Table 5.13), the BPS, CPOT, and FPRS tools offer several advantages. These can be used across different populations and settings, as there appeared to be significantly different scores between patients at rest and receiving either the non-painful or painful procedures. Based on the findings for the criterion validity of the scale's clinical applicability, there was a significant correlation between the FPRS, BPS and CPOT. Of note, the coefficient of the correlation for the concurrent validity between the BPS and FPRS is lower for the painful procedure than the non-painful procedure. Conversely, in the CPOT, the correlations between the procedures showed an expected drop for the non-painful procedure and an unexpected increase for the painful procedure. An examination of

the items of the scales showed high correlations for ‘compliance with the ventilation’ and total scores between the BPS and CPOT. More importantly, as identified by the effect size coefficients, all three pain scale scores were significantly higher during the painful procedure than during the non-painful procedure, with $p < 0.001$.

To understand and interpret the results from the validation study better, an exploratory comparison analysis using the “focus group” approach will follow. The outcome will be used to explain or support how certain external and internal factors affect scales use. The successful completion of phases 1 and 2 lead to phase 3 of the current study.

Chapter 6 Phase 3: Focus groups interview nurses

6.1 Introduction

The previous empirical results provide extensive support for the Behavioural Pain Scale (BPS), the Critical-Care Pain Observational Tools (CPOT), and Wong-Backer FACES Pain Rating Scale (FPRS) as a conceptual model of good psychometric properties amongst NVCPs. Based on their good reliability and ability to discriminate amongst known groups (non-painful or painful procedures), they exhibit an adequate capacity for detecting changes in pain. This study examines which pain assessment tool is the most appropriate to apply within clinical practice. The qualitative study expanded upon the quantitative study conducted in phase 2 for the comparisons between the BPS, CPOT, and FPRS.

The thesis structure is critical in conveying the logical approach used to explore the research questions. It demonstrates the feasibility and clinical utility of the three study scales. The chronological structure demonstrates that some results were not predicted, and that the method adopted in phase 3 is dependent upon the results from phase 2. Phase 3 of the study is designed to evaluate the clinical efficiency of the three scales obtained from the quantitative methodological approach (phase 2) from the qualitative perspective. By using focus groups (FGs) to explore the pain measurement practices of the PNs, the external and internal factors, as well as their significance as predictors of pain can be better assessed. The initial analysis of the results from the FGs is the health care providers' view of the feasibility and clinical utility of the three pain scales. Following this is an analysis of what constitutes overt

expressions of pain in NVCPs in accordance with the ICU nurse's opinions. The responses from the three focus groups (FG1, FG2, and FG3) will be reported in the form of group discussions. These are linked to the analytical sections, which also integrate the current literature on pain assessment.

6.2 Background

6.2.1 Nurse's views on behavioural pain assessments

Pain assessment in persons with an inability to communicate is a well-known challenge for professional caregivers. Within ICUs the world over, pain assessment has become problematic for registered nurses due to the changes in their role, which is now reaching beyond that of clinical practitioners. Nurses are now becoming consultant advisers to patients, their families and other health care staff. Pain behaviour is overt; it can be observed and recorded. In the past decade, several methods of behavioural pain assessment in adults have been developed and evaluated by researchers. There are also a few studies documenting knowledge and perceptions of pain assessment and management practices among ICU nurses (Payen et al. 2001, Ge linas 2009, Ge linas et. al. 2011, Rose et. al. 2012, Wysong 2012). The majority of ICU nurses do not use pain assessment tools for patients who cannot communicate and are unaware of the pain management guidelines published by professional societies (Rose et. al., 2012). Further education for hospital nurses related to pain assessment in NVCPs is needed (Wysong 2012). Several validated behavioural pain scales have been developed for NVCPs. Nurses agree that the BPS and CPOT can be easily taught and implemented in the ICU (Payen et al. 2001, Ge linas 2009, Ge linas et al.

2011). Unfortunately, these studies were based on self-administered questionnaire surveys. Questionnaires are standardised, so it is impossible to explain or expand on any points should the participants misinterpret them (Barbour RS 2005). It is also impossible to know how truthful a respondent is being. To obtain detailed information and avoid oversimplifying complex issues related to pain measurement, this unique study employed the FG approach to explore nurses' views on behavioural pain assessment.

In order to initiate phase 3, assessing the pain scales' utility, the research method requires the PNs to comment on the results of phases one and two. The structure and development of the research method are in part based on the outcomes of phases 1 and 2. These results were critical in guiding the exploration of the qualitative aspects. The sensitivity to the context of the use of the scales, the focus of the construct and the potential for human error are of significant interest. Currently, no studies exist that employ the FG discussion method; the following section discusses the importance and reasoning of the FG interviews employed in phase 3 of this study.

6.2.2 Focus group approach

Questionnaires are less likely to achieve the depth of information that is possible in an interview (Barbour 2005). Focus groups are in-depth, open-ended group discussions. They are conducted in order to allow research participants to exchange, discuss, agree or disagree about opinions, attitudes, and experiences (Parahoo 2006, Wibbenmeyer et al. 2011). Focus groups allow researchers to reach a degree of consensus on a topic and resolve key issues (Wibbenmeyer et

al. 2011). Face to face communication allows the interviewer to probe for information (Fellows & Liu 2003). The interviewer can seek clarification or expansion from the respondent when describing the practical implementation of pain assessment scales or by approaching NVCPs.

In-depth, qualitative interviews are excellent tools to use in planning and evaluating extension programmes. They use an open-ended, discovery-oriented method, which allows a deep exploration of the respondent's feelings and perspectives on a subject. Individual interviews and focus groups are the most common methods of data collection used in qualitative healthcare research (Gill et al. 2008). Both are intensively moderated, focused qualitative methodologies, with different strengths and weaknesses. General qualitative data are more convenient to collect in a short span of time using focus groups; by contrast, individual interviews allow in depth understanding (Harrell& Bradley 2009). Well-moderated groups simulate real-world dynamics (involving peer-to-peer interaction). However, individual interviews are more effective when exploring sensitive topics, and require less skill to conduct effectively (Harrell &Bradley 2009). Focus groups are an increasingly popular method of eliciting attitudes or opinions regarding sensitive, under-investigated topics (Barbour 2005). The benefit of this method is to identify beliefs, norms, and group culture (Krueger 1994). This phase of the study aims to collect data from the perspective of the nurses and the reasoning that underlies their experiences when employing the pain scales. Using FGs in this study is necessary to generate a richer understanding of nurses' experiences and beliefs with respect to pain assessment. The transcription method of FGs data is more complex and time consuming than

one-to-one interviews. Selecting the method of systematic analysis of FG transcripts is crucial (Gill et al. 2008). FGs usually involve eight to ten subjects (excluding the researchers), yet can work successfully with as few as three and as many as fourteen participants (Krueger 1994). As with research interviews, the interview agenda for FGs often consists of a loose schedule of topics to be discussed (Morgan 1998). To prepare an interview schedule for focus groups, Morgan (1998) summarised two general principles: 1) questions should move from general to more specific questions; 2) the question order should be relative to the importance of the issues on the research agenda.

To construct the interview questions, a list of the key aspects of the FG activities within the realm of the research focus is required. Twycross et al. (2011) carried out a FG in 2007 to establish nurses' views about the barriers and facilitators to paediatric pain management. The structured agenda concept established by Twycross (2007) was useful in guiding the logic of FG activities. The works regarding interview questions conducted by Payen et al. (2001) and two Canadian studies by Rose et al. in 2012 and Gelinias in 2009, exploring satisfaction levels using the BPS and CPOT, were used as references to structure the interview questions. The following section will explain in greater depth the collection of qualitative data and the issues associated with conducting FG interviews.

6.3 Methods

Due to the absence of research available for comparison, this study expanded on existing ideas and concepts where appropriate. New insights into the experiences

of nurses regarding pain assessment in ICUs were obtained. Based on the interpretative approach, the data generation and analysis led to an examination of the socio-cultural factors that may influence pain assessment in different hospitals. The thematic content and description of each issue was identified from the PN perspective. The PNs' views and experiences using the three pain scales for assessment in relation to their nursing profession as ICU nurses were further explored.

6.3.1 Aims

The primary aim of the present study was to ascertain the PNs' views with regard to the barriers and facilitators of effective pain management in NVCPs. This research was also driven by a secondary focus: an exploration of attitudes and perceptions with respect to pain and the assessment methods of nurses working with the BPS, CPOT, and FPRS in ICUs. To explore this focus, RQ4 and RQ5 were addressed in Section 3.2. RQ3, which addressed the responsiveness of the scales, has been addressed with important implications for investigators. RQ5 addresses the PNs' preferred scale and follows from RQ4, which explored the similarities between the scales.

6.3.2 Setting and subjects

Prior to the data collection, approval from the ethics board of each hospital was sought and granted. The study aims to identify the views of the PNs with respect to pain assessment in NVCPs. Of particular interest is the relation to the nursing profession where the use of the BPS, CPOT, and FPRS is most likely to be employed. The FG participants were the PNs who had participated in phases 1

and 2 of the original study. The selection criterion for the FG participants was addressed in section 5.3.10. Due to the impact of shift work on the PNs and their different jobs, it was a challenge to arrange a meeting with the PNs. The total number of participants in the FG was eleven PNs, as many chose to withdraw from the study for personal reasons. Eleven PNs were included in the FG interview (Figure 6.1), separated into three groups, FG1 (n=4), FG2 (n=4), and FG (n=3), in northern, central and southern Taiwan respectively.

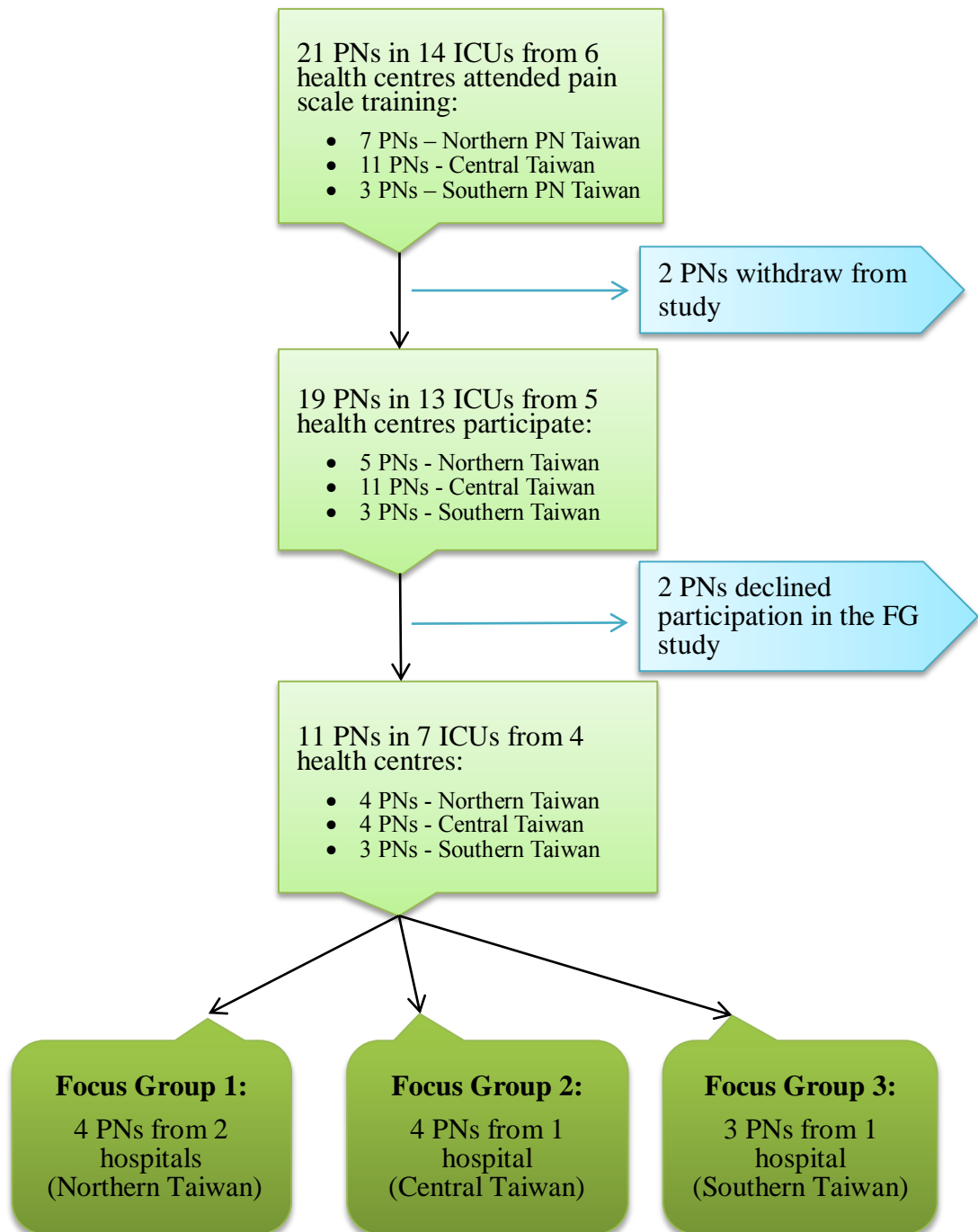


Figure 6.1 Focus group development: PN recruitment in phase 3.

Prior to the descriptions of the results (see Chapter 5), this section introduces the PNs in more detail. A purposive sample of eleven PNs with intensive care training, working in 5 hospitals in northern, southern, and central Taiwan were invited to participate. The participants were all women aged 24 to 45 years, and all had experience of working as RNs in hospitals ranging from two to twenty years. Of the eleven participants, one was an RN. The remaining participants were identified as RPNs within the Taiwanese nursing health care profession. Of these ten RPNs, one is also a certified Registered Respiratory Therapist (RRT), one a clinical nurse manager in a surgical ICU, and another the assistant nurse lead in a medical ICU. Two were clinical nurse specialists in neuro-medical and neuro-surgical health. Nine hold bachelor's degrees in nursing and one of these is an RRT. Two hold college diplomas. All staff are native, raised in Taiwan and educated in the Taiwanese nursing school system. During the period of the study, they were employed full time in ICU settings.

Due to the geography of the study, FG interviews were conducted in northern, southern, and central Taiwan, while the phase 2 data collection continued. The data collection and FG interviews spanned a nine month period in northern Taiwan and lasted 1 year and 5 months, respectively, in central and southern Taiwan. The potential differences in familiarity due to the amount of time for which the PNs has worked with the pain scales were accounted for in the data analysis.

6.3.3 Procedure

Phase 3 of the research requires data collection from the PNs via semi-structured interviews. Phase 3 aims to: 1) establish pain behaviour (if any) that can be observed in NVCPs, and 2) establish the practicality of these pain scales in the clinical implementation to see if any pain scale is valid. To satisfy the requirements of the first aim, two approaches are possible: unstructured interviews requesting the PN to list the overt expressions of pain observed in NVCPs. This approach risks the PN remembering only some types of behaviour related to NVCPs suffering pain. The second approach eliminates selective recall by providing a list of different types of pain behaviour and requesting the PNs to indicate the items on the list they have observed in their experience. The risk with this approach is that not all types of pain behaviour are listed, as they may not have been recorded in the literature for inclusion. To reduce the risks related to the second approach, a semi-structured interview, which included a list of overt expressions of pain, may be used as a prompt. This list is then supplemented with open ended questions which allow the PNs to describe their observations in detail.

The focus group conversations were conducted in April 2012. A total of eleven PNs confirmed that they took part in phase 1 of the study and they accepted the invitation to participate in the interview. They came from various ICUs and different areas of Taiwan. There exist many challenges when conducting FG interviews, due to the nature of shift work in the direct care settings. Conducting focus groups with nursing staff requires careful planning.

The interviews were conducted on their days-off to minimise PN discomfort and enrich the data. Before starting the data collection, the study also obtained ethical approval for this part of the study. The PNs were informed that the FGs were part of the full study currently being conducted and that the aim of the FGs was to ascertain their views in this context. The principal investigator moderated the FG interviews. The moderator's role is to guide the conversation and encourage the PNs to share their experiences. The PNs were given an interview guide in the form of a flipchart and informed that there were no right or wrong answers, as it was their truthful opinions and experienced of the use of the pain scales that were of key interest. Each FG meeting required 30-45 minutes to fulfil the interview agenda. The FG meeting procedure is outlined in Figure 6.2.

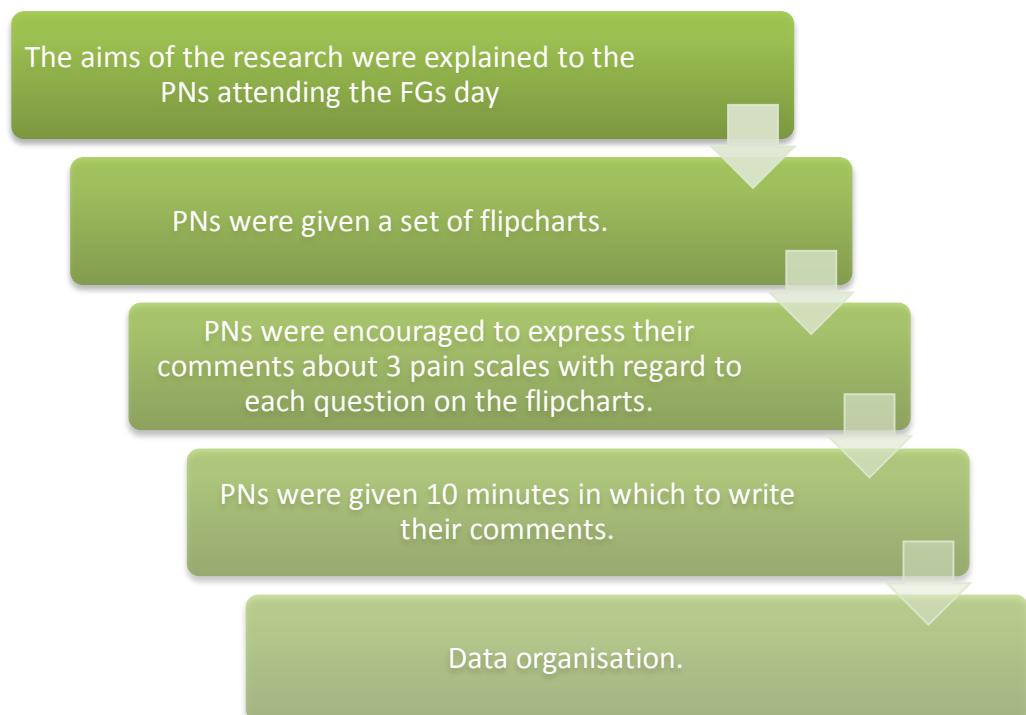


Figure 6.2 Procedure for the focus group interviews in the study.

The FG participants received flipcharts containing open-ended investigative questions (Table 6.1). Two main questions lead the interview, with follow-up questions to address possible outstanding aspects (Table 6.1).

Table 6.1 Focus Group Questions

Main questions	Follow-up Questions
What have been your experiences of pain assessment of NVCPs?	<ul style="list-style-type: none"> • How would you describe NVCPs' overt expression of pain, in your experience? • What would help you to manage pain in NVCPs more effectively?
What is your opinion and experiences of using the BPS, CPOT, and FPRS with NVCPs?	<ul style="list-style-type: none"> • How useful is the BPS in supporting your decision making about pain management in NVCPs? • How useful is the CPOT in supporting your decision making about pain management in NVCPs? • How useful is the FPRS in supporting your decision making about pain management in NVCPs? • Which of the BPS, CPOT and FPRS do you think provides the most useful information for creating an effective pain management plan for NVCPs?

Investigative integrity is particularly challenging in situations involving a potential power imbalance or when revelation may expose compromised care quality (Dimopoulou 2005). The PNs were provided with blank sheets as part of the flipcharts to record their views if they felt reluctant to defend their view in front of the group. The interview was audio-taped for later verbatim transcription and notes were also taken by a research assistant who observed and reflected on

the nurses' interactions. The focus of the research assistant was the manner in which the PNs agreed, disagreed, negotiated or generated meaning in terms of the subject investigated. Each FG ranged in length from 30 to 45 minutes.

6.3.4 Data analysis

After each FG, a report describing the discussion for the assessment work group was written by the moderator. The report contained the questions that had been raised by the discussion guide. The FG sessions were recorded and then later transcribed on an individual basis. The transcription was then analysed in order to identify recurrent themes across the three FGs. The questions on the agenda are focused on revealing the subjective responses and experiences of the PNs to the BPS, CPOT, and FPRS. These responses are important in contributing a deeper analysis for understanding the main results of the second phase of this study.

FGs produce direct data on consensus as well as diversity by providing the opportunity for participants to reflect on and react to the opinions of others (Herdman *et al.* 1997). As the FGs data collection started, the researcher reviewed the data, made notes on them and began to sort them into categories. Styled as a data analysis strategy, researchers move the analysis from a broad reading of the data towards discovering patterns and developing themes. Thematic analysis in its simplest form is a categorising strategy for qualitative data (Braun & Clarke 2006).

Thematic analysis of the views of PNs, with respect to the three pain scales in clinical practice, is necessary. One aim of the present study is to understand in

detail the clinical utility of the BPS, CPOT, and FPRS through PNs' experiences. Based on the oral feedback in the FGs, the generalisation of their ideas regarding these pain scales is the goal. For that purpose, thematic analysis provides a flexible method for getting close to the data and developing a deeper appreciation of their content. It also makes it possible to adjust the research intentions and analysis process (Braun & Clarke 2006).

Using thematic analysis may inadvertently reflect the author's opinion or bias and raises questions about human nature, as well as the meaning of human experience (Ritzer 2009). Although the initial themes may not be in conformity with those of another analyser, if skilfully written, the work may still identify a theme that illuminates some aspects of true human experience (Ritzer 2009). A more specific thematic analysis procedure involves the gathering of information regarding the PNs' experience by identifying concepts and comparing and contrasting data.

Through referencing the literature, the investigator gains information that allows inferences to be drawn from the focus groups. Once the themes have been collated, the researcher is ready to formulate thematic statements to explain the results.

After the three FG meetings, the data were analysed using thematic content analysis. The data from the flipcharts were collated into a Word document. The analysis started with careful verbatim transcription, including stops, intonations and overlapping speech, in order to understand the PNs' perspective both as members of a group and of the nursing profession (Table 6.2). The data were

read several times to identify recurrent responses that could be placed into themes or categories, as advocated by Twycross and Shields (2008). This was done using Nvivo 9.0 software to highlight the text according to themes, cutting, pasting, and then collating the data. This allowed the identification of emergent themes from within the data.

Table 6.2 Transcription Conventions Used

Symbol	Indication
Underline	Overlapping/concurrent speech
Comma “,”	Continuation
Dot “.”	Conclusive intonation
Hyphen “—“	Interruption
Bold	Emphasised speech
CAPITAL	Loud voice volume
Double Parentheses (())	Sound marker
(.) (..) (...)	Pause marker, for shorter and longer pause
Brackets []	Words in brackets indicate researcher’s comments, not transcriptions

A comprehensive view of the information occurs when the follow-up questions are addressed. At this point, a pattern within the responses clearly emerges. Using the pattern as a guideline, it is best to obtain further feedback from the PNs about the point in question. This is possible either while the interview is taking place or by requesting further feedback from the PNs based on the transcribed conversations. This feedback is then incorporated into the thematic analysis.

The phase 2 analysis served to answer the research questions concerning the utility of the BPS, CPOT, and FPRS. The identification and categorisation of all processes related to learning about and using the pain scales in clinical practice were based on Miles and Huberman's (1994) suggestions regarding the coding of qualitative data. The process required several iterations prior to completion. The principal investigator read the transcriptions to obtain a general impression of the interviewees' responses. Then, next to each line or paragraph, labels were generated to reflect the initial coding. Based on these labels, the study generated a category scheme of the participants' responses.

To organise the data, themes were identified by sorting the initial schemes into concrete categories and subcategories. The categorisation reflected the similarity of responses (in regard to the pain assessment process) and frequency of the responses. Next, the investigator re-read the transcripts and field notes, while checking for frequently occurring expressions. At the same time, any unexpected, counterintuitive material that provided atypical evidence of the participants' experiences was also noted. The responses were then categorised according to

several initial themes, i.e. “BPS and CPOT were more practical in terms of the application of the scale than FPRS”, “CPOT was less accurate and more complicated than BPS”, and so on.

These themes were then reviewed to determine how they fit into the existing pain assessment theory and how they may contribute to our understanding of the pain measurement process. Two criteria were incorporated: 1) Does the information confirm current pain assessment theory and practice? 2) Do these data offer new insights into an interpretation of the new pain assessment tools? As a result, the initial themes were combined and renamed as two main dimensions regarding the pain assessment tools. Finally, the study re-read the responses and categorised them into one of the two main themes to ensure a good fit. It was then determined that the resulting two main dimensions adequately reflected the responses provided by the PNs.

6.4 Results

Table 6.3 summarises the results — explaining exactly what is going to be explored and how. Then the section is organised around RQ4 and RQ5 in the same order as in the methods and in the above table, describing what has been done and explaining the extent to which the results are verified.

Table 6.3 Summary of the results for phase 3 of the study.

Study Aims	Finding presentation
RQ4. What is the association between the BPS, CPOT, and FPRS when used to rate current pain?	Nurses' cognition on overt expressions of pain in patients who cannot communicate verbally.
RQ5. What is the scale preference considering patients with non-communicative status, critical illness, and clinical practice in the ICU setting?	Feasibility and clinical utility of the BPS, CPOT, FPRS.

The quantitative data from phase 2 are used to prove the validity and reliability of the BPS, CPOT, and FPRS in NVCPs. It is also the starting point from which the qualitative data were collected using the FG interviews.

The following sections highlight the perspective of the PNs and their experiences of pain assessment with NVCPs in ICUs. Two major themes emerged from the data:

1. PNs' recognition of overt expressions of pain in NVCPs.
2. The feasibility and clinical utility of the BPS, CPOT, and FPRS.

The findings from the PNs' views in FG1, FG2, and FG3 are reported in sections 6.4.1 and 6.4.2. The results are listed and illustrated using quotations from the FGs.

6.4.1 Overt expressions of pain in NVCPs

Changes in a patient's ability to communicate verbally will present special challenges when treating pain. It is important that health care providers involved in a patient's care are aware of his or her specific pain behaviour. If not, health

care staff may fail to recognise when a patient, who cannot self-report, is in pain. They will also be unable to assess if the pain scale in use is efficient at rating the pain intensity of the patient.

“Although pain is a personal and subjective experience, the fact that someone is experiencing pain is often apparent to others. People who have pain may vocalize their distress by moaning, crying or complaining, or may exhibit pain-related body postures or facial expressions. These verbal and nonverbal behaviours have been called pain behaviours because they serve to communicate the fact that pain is being experienced (Fordyce 1976).” (Keefe et al. 2001, p. 170, emphasis added)

Patients display a broad range of reactions, some of which are controllable, while others are not. They remain indicative of pain, distress, and suffering. Autonomic response activity, such as a rapid heart rate or perspiration, may indicate the presence of acute pain. However, these physiological signs habituate and their absence cannot rule out pain. Table 6.4 outlines overt manifestations of pain that have been labelled pain behaviour by the PNs in the FGs, based on their clinical experiences.

Pain behaviour is a functionally equivalent manner that communicates information. Various forms of pain behaviour are equally susceptible to intra- and interpersonal influences. When patients cannot express their distress verbally, it is important that the observations by a health professional are clear with respect to the features that convey the most information as an expression of pain. Four categories and twelve types of pain behaviour were identified to describe the PNs’ observations of pain behaviour in their clinical experience.

Table 6.4 Overt expressions of pain behaviour in NVCPs

Manifestation	Behaviour	Source	Frequency
Autonomic response activity	Change of vital signs from baseline	3	8
	Change in breathing patterns	1	1
	Resisting ventilation	2	4
	Irritable disposition	3	5
Communication	Sighs, moans	2	8
	Body movement	3	7
	Facial expression, e.g. grimacing	3	8
Attention seeking behaviours	Need for more pain medication	1	2
	Reject of treatment or reduction of activities	3	3
Protective behaviour	Defensive, guarded posture	2	3
	Protective manner	2	5

6.4.1.1 Autonomic response activity

Some research has noted that pain is a subjective experience, and not objective. Therefore, the demonstration of changes in vital signs from baseline may not be a pain response (Arbour & G  linas 2010). However, most of the PNs reported that changes in vital signs usually refer to pain, as perceived by the patient:

PN1, FG1: *‘Pain is subjective, if they are unable to verbally express themselves, the FPRS may be the only subjective assessment for nurses. The only source of information for pain assessment is from a patient’s facial*

expression. So it may easily become a nurse's subjective judgement based on his/her experience. I think the scale can add another source from the patients, for example, the measurement of some vital signs or physical action, it should be a more objective measurement.'

PN2, FG1: *'... I think that the measurement of Vital Signs can detect the patient's pain, in view of comparing vital signs with baseline values. It doesn't mean we can grade the pain at a high level just because his vital signs are high. If the patient has high blood pressure, then perhaps this judgement may be less objective. I think the subjective assessment will still have some relevance...in my unit, we usually monitor the changes in Vital Signs of patients, like 2T [GCS score for unconscious with mechanical ventilation] patients, so we also mainly see their vital signs, and compare this with the more usual changes.'*

One PN, who had been in the profession for only a short time (a year), noted that pain might be a factor in altering a patient's breathing pattern:

PN1, FG1: *'... Breathing patterns, when the patient cannot speak...we may use his breathing patterns as a reference. Like, say, he may use some parts of the respiratory muscles...The depth, the length of his breathing may change...sometimes he may have asthma....If it is really a patient in pain, basically, this breathing pattern will become longer and shallower...'*

In the following quotation, PN1 questioned above reversed her statement by adding that considering the difference in breathing pattern might bias the pain assessment. She based this on the fact that differences in breathing patterns might vary from one person to the next:

PN1, FG1: *'...But I feel like...Ah, everybody is different. In fact, like when I'm in pain, I feel like I'm suffocating. I think this indicator is not objective. The shades are very subjective, the depth of breathing is difficult to objectively*

assess, because the behavioural indicators of each person should not be regarded as meaning exactly the same thing...'

When the PNs described what they observed, what usually appeared in their reports on NVCPs were the phrases “Against ventilation” and “Irritable disposition” as the main signs of pain in patients:

PN1, FG1: *'Some behaviour, for example...we sometimes do invasive treatment and cause pain, Some people may be in bed for long periods of time and may develop restless peristalsis, become very irritated, sometimes it will be deemed to be a pain indicator, or some such behavioural change...he usually is, for example, very gentle, or always in compliance with caregiver or treatments. But when he suffers from pain, he suddenly starts fighting with the ventilator, or...he wants to break free of the constraints or other restless behaviour appears.'*

PN2, FG1: *'...For those patients who cannot speak, this does not necessarily mean that the speechless person will be given mechanical ventilation. The cough may be used to assess the patient's pain...'*

6.4.1.2 Communication

From a group perspective, the PNs reached a consensus in terms of what the main forms of verbal communication and direct communicative behaviour meant. Behaviour such as sighs, moans, body movements, and facial grimaces was noted and assessed:

PN1, FG1: *'we usually assess the condition of the patient, in addition to seeing facial expressions, many patients will groan, sigh, and moan...but there is no way to hear the sound of patients with intubated ventilation. In addition, we will see whether the patient is very restless or not, and what their activity levels are like...look at some of their vital signs for signs of change...'*

PN2, FG3: *'for coma patients, we will use some indicators, such as basic vital signs, facial expressions, body movements, and breathing compliance with mechanical ventilation. In fact, I feel these assessments have been considered quite complete...'*

Nevertheless, some of the PNs lacked an understanding of patient behaviour. For example, it may be difficult to recognise changes in facial expression during pain, if the patient always looks worried:

PN1, FG3: *'Facial expressions can be a direct way of assessing pain, but there are many factors influencing facial expression that may not be linked with pain ...'*

PN2, FG3: *'For example, before the patient was clear, he may display some special actions or expressions to express pain. But then he was intubated, and we sometimes need the family to help us recognise his pain from his behaviour.'*

6.4.1.3 Attention seeking behaviour

Once the patient is unable to communicate verbally, there is the risk of health care staff displaying a potential lack of sensitivity or lack of attention to patients' attention-seeking behaviour. This deficit can threaten effective pain management. The PNs reflected on the forms of communication used during pain assessment. Further to assessing pain in NVCPs, the PNs in FG3 focused on the non-verbal aspects of communication with ICU patients and the identification of indicators:

PN1, FG3: *'...in compliance with the treatment, it can be an indicator. For example, if he does not want to turn, this is because changing position may cause pain.'*

PN2, FG3: *'The original use of the drug for him seems to have no effect, he may be less and less easy and compliant with the treatment, and may require each dose of pain relief to be incremental. So, you need to give him more and more analgesics, even if it is used merely for calming purposes. Ah...because he will request more and more the scores get higher...For example, by injecting 5mg analgesia into the patient, this situation now presents his pain score as 8 points. After an interval of another week, we are still giving him the same dose, but now he scores 10 points. It means that, even where the patient's pain threshold seems to decrease, his pain scores would in no way indicate his pain as usual.'*

6.4.1.4 Protective behaviour

The 'Protective Behaviour' category is a combination of a 1) "Defensive, guarded posture" and 2) a "Protective manner". Based on their perceptions of protective behaviour, the PNs discussed body movements in order to highlight any situation in which they feel that a patient is worried or unsafe. Feelings of stress, being bullied or threatened were explored, as well as how to ameliorate this sensation for the patient:

PN1, FG3: *'...Yes, patients may rub or touch the most painful site, or will want to protect the most important place...like protective action.'*

PN2, FG3: *'Sometimes he cannot speak, or he cannot express himself because of intubation. When I see an absence of movements, but he is still curled up in that position and is scared to turn over, or he has curled his body up into a protective ball, we know that he is in pain...'*

The PNs identified a number of overt expressions of pain behaviour related to biomedical, psychological, and social factors. Of note, there was no mention of the biomedical response of muscle tension to pain behaviour during any of

the FG discussions. This may explain the PNs' suggestion that the subcategories "Body Movement" and "Muscle Tension" in the CPOT should be integrated into one item.

6.4.2 Feasibility and clinical utility of the BPS, CPOT, and FPRS

Feasibility and clinical utility are essential considerations. These can lead to the development or selection of a pain scale for practical implementation. Through their understanding and insight into the scales, as utilized in the ICU, the PNs in the FGs were able to highlight various aspects that are important to the current study. The theme of feasibility and clinical utility is then subdivided into nine categories based on the FG discussions.

6.4.2.1 The BPS is easy to learn and use

The PNs' perspectives on how the pain scales would help them to assess and understand pain in NVCPs when using the BPS is based on two factors: 1) "easy to learn" and 2) "easy to use". The two main strengths of the BPS as perceived by the PNs were: 1) the BPS focuses on the appropriate points for pain assessment, and 2) the clear and simple statements. The respondent is required to evaluate the pain levels, with obvious distinctions made between the points on the subscales in terms of variation about the mean:

PN1, FG1: The BPS is quite easy to use...the items are presented in a simple manner, the assessment will not involve too much work...and its contents are easier to grasp [the PNs present at the meeting nodded their assent with this]. You can analytically compare a patient's pain condition from changes in their scores and consequently you can understand whether there has been progress

in his pain relief or not. And, there [on the BPS] are not too many items. So, you do not have to spend too much time...It [the BPS] is simple...and you can complete it very quickly. And then you can see the changes in pain from the differences in the scores. I find it quite easy to use.

PN2, FG1: *'...the execution of the BPS was simple, the project was well explained and easy to follow because its content and the level is very clear. I didn't have to spend too much time...Another PN said: completed it very soon...I only needed to take a glance at its descriptions; it was easy to recognize what point I should give...'*

PN3, FG1: *'Well, it [the BPS] is easy to use...assigning the scores is easy as the descriptions are very clear...the assessment time does not take long...'*

PN1, FG2: *'Details of the BPS will be kept brief...[one participant interrupted her: 'it is not that complicated...'] It is very easy for everyone to understand, and the users can quickly assess the patient's pain.'*

PN2, FG2: *'that one [she held up the BPS documents] is easier for everyone to use. Between the BPS and FPRS, I prefer this [she pointed at the BPS documents]. I think the FPRS is less effective than the BPS. This [the BPS] is simpler than the others because I can immediately grade the patient's pain when I see him. I can quickly assess the level of pain of the patient. Is he/she really in severe pain? As a result, I can easily make a decision about what treatment should be given regarding his/her pain. I also think other clinicians [doctors] will prefer to use the BPS for pain assessment.'*

PN3, FG2: *'...you can very quickly assess the level of pain of the patient if you use the BPS.'*

PN2, FG2: *'Just feel...the BPS is more accurate in assessing a patient's pain. This is my viewpoint...'*

PN1, FG 2: *'The **BPS** is the best tool for assessing a patient's pain level (...)'*
[the two others participants responded at the same time and smiled in

agreement with her statement].

6.4.2.2 “Upper limb movement” of the BPS should include lower body movement

While the BPS is well-received by the PNs in the ICU, a major disadvantage was also revealed. Patients who were receiving protective physical restraint cannot be accurately described and measured with regard to “upper limb movement”. Forced immobility may be effective in protecting them from pain caused by movement; however, this lack of movement may become a misinterpreted indicator. This has been noted in the literature, where nurses have identified the absence of movement as an indicator of the presence of pain in ICU patients (Puntillo et al. 1997). Body movement is known to vary depending on the patient's level of consciousness and physical factors (e.g., use of physical restraints, medication). The use of physical restraint is usually linked to delirium in ICU patients in order to prevent self-extubation. Physically restrained patients will find it difficult to indicate their pain by expressing it through moving their limbs. In particular, the use of physical restraint is often applied to the upper extremities of patients in ICUs. Hence, three nurses suggested that the “upper limbs movement” subscale should be extended to include the lower limbs:

PN1, FG2: *‘Does the description only refer to a patient’s upper limb movements? Because the physical restraint of the upper limbs is a common intervention in ICUs...[others participants definitely said yes, combined with a smile]... The patient’s lower limbs will not often be restrained. Hence, I am confused why patients sometimes kick while they are receiving a suction*

intervention as their arms have been restrained. So, can I assess the patient's pain behaviour based on the movement of their legs...as lower limbs?'

PN2, FG2: *'I think it should be more descriptive about the section of upper limb movement since it is sometimes impossible to expect a patient to stay still while performing suction intervention. If he/she moves slightly, you may think...a mild movement; you may take it as a very minor response. It is very difficult to decide the score you should assign. In my experience, I do not know how to decide the pain score for the section on upper limb movements, whether he/she has moved his limbs or not...'*

When PNs used the BPS for pain assessment, they stated that it was difficult to differentiate between levels 1 and 2 on the subscale of upper limb movement:

PN1, FG2: *'Mild movements of a patient's limb may indicate either painlessness or mild pain. If it is very obvious, then I can probably mark it "3" once patients move their limbs vigorously. However, you will have no idea whether you should mark it 2 or 1 if they only make a slight movement. You will hesitate to give it a score.'*

PN3, FG2: *'...it is sometimes very difficult to assess whether it only refers to the upper limbs, or the difference between levels 1 and 2 she has just mentioned...'*

6.4.2.3 The CPOT includes operational definitions for the levels of pain

In contrast to the BPS, there are more behavioural items in the CPOT. Additionally, the CPOT items are rated on a three-point scale, in which the scores have clear definitions. The PNs stated that the CPOT provided them with a significant level of detailed and itemized descriptions for assessing pain

in NVCPs. Consequently, the PNs felt that they could rapidly and explicitly indicate their patients' pain level. As such, the PNs thought that the CPOT is a good pain assessment scale for scoring pain in NVCPs:

PN1, FG1: *'...I think that the item descriptions of the CPOT are more detailed than the others...'*

PN1, FG2: *'it is clearer... Yes, the description of the CPOT...the description about pain behaviour...I think its description provides more detail...'*

PN1, FG3: *'The CPOT I think is relatively simple since it is clearly described. The indicators are direct...the pain behaviours are clearly indicated and so is the scoring system...I mean that you can quickly decide what level of pain the patient has...'*

PN2, FG3: *'It is a little more than that...the CPOT is ahead of the scale with three items [referring to the praise for the BPS]. This is due to the breakdown...Another participant interjected: it is presented more completely...it is quite detailed...We feel that it is good. It is very clearly written and very easy to score. Therefore, we think that it is easier to complete, and will be recommended to the hospital. [Both said that they feel that the CPOT is better and more complete, providing detailed descriptions as well as differentiating between the indicators. They would recommend the CPOT.]*

6.4.2.4 The CPOT scoring is less user-friendly

The main inconvenience related to using the CPOT was the difficulty in assigning the scores for "Body Movement" and "Muscle Tension". The choice between scores 1 and 2 was extremely difficult to assess. The PNs stated that the CPOT descriptions were insufficiently clear to allow them accurately score the patient's pain accurately. The CPOT uses the words 'tense' and 'rigid' and ratings of 1 or 2. However, a patient must be observed to be "very" tense and

rigid to receive a score of 2. The definition and observation of tense and rigid differed amongst the PNs. Quantifying “tense”, “rigid” and “very” in this context remains to be resolved. As a result, the PNs felt that they needed to spend more time thinking about how to distinguish between the points for each item. Some PNs also found that confusion about pain behaviour regarding “body movement” and “muscle tension” was a more prominent problem when assessing pain using the CPOT. This similar predicament was unrevealed in the BPS. The PNs could not accurately score the patients’ pain behaviour for the “body movement” item as these patients were under physical restraint to prevent self-extubation. As such, the PNs reported a bias against using the CPOT due to the unclear coding. Further, due to the lack of clarity and definitions used in the CPOT, most of the PNs felt that it was inappropriate for use in ICUs:

PN1, FG1: *I think there is too little spacing in the ratings of...is 0, 1, 2... there is no intermediate level...because the spacing is not defined and it is not very clear...in the timed assessment...the range of options is too narrow to say anything meaningful...sometimes, you are forced to be vague...you want to score higher, but it seems that a score of one is not enough in compliance to describe a little change...or it seems that it lines up with neither one point nor the other. It falls into a gap between two points on the scores [One participant nodded in agreement: there is still a slight difference]. There is another...item 3 [muscle tension, the BPS does not have that item], and I think that seems to present a difficulty when making a decision. You want to say, the patient is in a little pain...so his muscle tension may increase, while in other patients it will not [one participant whispered. “Some really do not like to use that”]. I think it is a bit redundant...’*

PN1, FG1: *'... In clinical practice, the CPOT should be a useful tool because it only has three levels: 0, 1, 2...there is a difficulty in making clear judgments on pain level when I assess a patient's pain because it is hard to distinguish the difference between points 0 and 1. For example, in practice, there is no outstanding difference in pain behaviour between the CPOT items' descriptions of points 0 and 1'.*

PN2, FG1: *'For example, patients may have physical restraints, because suctioning may cause restlessness. We cannot release the patient from his restraints to assess his muscle strength; in fact, that part will be skipped ...'*

PN3, FG1: *'... based on the feasibility in clinical practice, it remains difficult to use, especially in emergency ICUs. The gap is still the same, with unclear spacing between the pain ratings.'*

PN1, FG2: *'I think what made me stop is the issues related to body movement are. This is because, when you give a stimulus to a patient or touch him/her, his/her limbs certainly respond in some way, such as relaxing [spreading her arms], tension [partially bending her upper limbs], or rigidity [fully bending her upper limbs with finger flexion]. The CPOT is...ambiguous. The reason is that their body must present reflexes due to the stimulus. However, I may be stuck about what scores to give if I find that the patient did not present a strong reflex.'*

PN2, FG2: *'I need to spend some time double checking...Although the CPOT has detailed descriptions; it requires us to double check and recall whether the behaviour of the patient matches the description of the items in the CPOT. Therefore, there may be an error or difference due to the re-assessment...'*

PN1, FG2: *'It takes a while for me to recall what the patient's condition is compared to his/her pain level. When I go back to have a look at the patient, I may ask "why? It seems that something has changed." Then, I shall start questioning the accuracy of my assessment.'*

6.4.2.5 The two subscales of the CPOT should be integrated together

The PNs felt that the CPOT was insufficiently clear to allow them to score their patients quickly. They suggested that the CPOT integrate the subscale “muscle tension” with the subscale “body movement” for ease of use:

PN1 FG 1: *‘In the assessment of the Body Movement section, there will be a vague zone. In that part of the assessment, it is easy to get confused about how to score the patient’s pain. I think the items Body Movement and Muscle Tension...are, in fact, very similar. So I would suggest that the body movement and muscle tension parts of this scale [the CPOT] be combined ...’*

PN2 FG 1: *‘For example, patients may receive physical restraint, because suctioning may cause restlessness. We cannot let the patient out of his restraint to assess his muscle strength; in fact, that part will be skipped ...’*

PN1 FG 2: *‘I think what made me stop is what the issues on body movement are. This is because, when you give a stimulus to a patient or touch him/her, his/her limbs certainly responds in various ways, such as relaxing [spreading her arms], tensing [partially bending her upper limbs], or going rigid [fully bending her upper limbs with finger flexion]. The CPOT is...ambiguous. The reason is that their body must present reflexes due to the stimulus. However, I may be stuck as to what scores to give if I find that the patient did not present a strong reflex.’*

6.4.2.6 The FPRS is easy to use but the PNs question its reliability

The FPRS is commonly used in current clinical practice (Pierrick et al. 2007).

As the PNs are familiar with the BPS and CPOT and their application in practice, their opinion of the FPRS was of note. The PNs stated that it was not rigorous enough to assess pain in NVCPs with validity. The FPRS relies on narrowly-defined parameters for pain behaviour. The PNs expressed concern

regarding the potential for considerable bias between the estimated scores and the reality of a patient's pain. Interestingly, when PN1, FG2 offered her comments, others in the same group used humour to expand on her thoughts, typically laughing loudly and nodding together. These focus groups raise issues which are relevant to their experiences in their profession and often express similar views:

PN2, FG1: *'The FPRS is straightforward, but its accuracy is questionable...'*

PN1, FG1: *'The FPRS is **not** analytical enough to know what or how the patient suffers the pain stimulus, because it measures only one aspect of pain behaviour. If the patient always has a WORRIED face, it is difficult to recognise changes in his/her facial expression during pain. [All participants laugh loudly.]*

PN3, FG1: *'Yes, it would affect my judgement; when he/she is already grimacing and therefore I'll underestimate his/her pain score.'*

PN1, FG2: *'Um...it is less precise than...Right! That is because some patients might exaggerate their facial expressions. [One participant nods and bursts out laughing]. He/she might make **a lot of facial expressions**...[All participants laugh loudly]...He/she may only feel pain in his face but not his limbs. For instance, some patients may be very sensitive to touch in their eyes when we carry out eye care. **Only a touch** may make them **blink vigorously** but they actually **DO NOT** feel much pain. [She brandished her hands in front of her eyes and seemed quite annoyed. The other participants watched, smiling and nodding.] Therefore, the FPRS is relatively less—[a partner interrupted her: 'objective evaluation in assessing a patients' pain'].*

PN2, FG2: *'The FPRS is relatively less...objective an evaluation in assessing a patients' pain...Yes, the scores of the FPRS may deviate greatly from the*

actual level of the patient's pain if the patient shows many facial expressions but very limited limb movement.'

PN1, FG3: *'...the FPRS can be considered the most common in use and should be counted the most acclaimed, but [laughs]...I feel that it is very easy to observe, then it is also very direct...[sarcasm].'*

6.4.2.7 The BPS and CPOT are more practical in application than the FPRS

Based on their experience of working with the three pain scales in the first phase of the study, the PNs were able to make a general comparison of the scales when used on NVCPs. The seven PNs in the three focus groups indicated that both the BPS and CPOT were of more practical application than the FPRS for evaluating pain in NVCPs:

PN2, FG2: *'Between the BPS and FPRS, I prefer this [points at the documents on the BPS]. I think, because the FPRS only has one dimension, it is less effective than the BPS. This [the BPS] is far simpler than the others because I can immediately grade the patient's pain when I see him. I can quickly assess the patient's pain level, whether he/she is really in pain...'*

PN1, FG3: *'... In fact, if you are looking at it from the patient's point of view, the BPS and CPOT...should be more accurate than the FPRS...more closely tied to the objective of pain reporting. Well, if you are looking at it from the patient's point of view, ah. The more detailed the better...'*

6.4.2.8 The BPS was clearer and more specific than the CPOT

The PNs described their opinions in terms of how convenient each of the three pain scales were when used on NVCPs. The FGs' data reported that the BPS provided a clear description for each item and was more specific in assessing

the patient's pain than the CPOT. As these PNs were familiar with the use of the three pain scales, their opinions are significant. The PNs in FG1 preferred the BPS, as each of its items is easier to understand than the CPOT. The PNs in FG2 indicated that the BPS was a more useful scale for evaluating pain intensity, when compared to the CPOT:

PN1, FG2: *'Although the CPOT has detailed descriptions, that one [she held up the documents about the BPS] is easier for everyone to use.'*

PN2, FG2: *'If the tool needs to be appropriate for various patients, the details of the BPS must be kept brief...[a participant interrupted her: 'it is not that complicated'...]. It is very easy for everyone to understand, and users can quickly grade the patient's pain. That one [pointing to the CPOT paper] requires you to read detailed descriptions and cross check at the same time...'*

PN3, FG2: *'In my clinical experience, I think the CPOT is more complicated...it means you need to assess a patient's pain, while referring to the scale. I only need to observe a patient's facial expression when I use the FPRS. Er...I only need to observe the patients' behaviour when I use the BPS to assess their pain. But, this scale [the CPOT] has many sections. I feel like there is not enough time to finish it, and I also need to mark down their vital signs, etc... I think it is less accurate compared to the BPS. I just feel...the BPS is more accurate in assessing a patient's pain. This is my point of view. I find it too complicated'.* [The other participants look at her and nod].

PN3, FG2: *'I spend more time double checking [she pointed at the CPOT]...Although the CPOT provides detailed descriptions, it requires us to double check and recall whether the behaviour of the patient matches the description of the items in the CPOT. Therefore, there may be errors or differences due to the re-assessment...'*

The FG3 perspective is slightly different than that of FG1 and FG2. The PNs stated that the CPOT was easier to use and provided clearer descriptions of the items than the BPS. Interestingly, FG1 and FG2 initially stated that the CPOT was easier to use than the BPS. However, after nine months using the CPOT in ICUs, the PNs reversed their initial opinion. Strikingly, FG1 and FG2 have worked with these pain scales for more than nine months. FG3 was able to work with these scales for a total of 5 months only. It is reasonable to assume that, had FG3 been able to continue with the study, their opinions might have been reversed in preference of the BPS:

PN1, FG3: *'...the BPS has a relatively bleary-eyed zone or lacks specifics in this [descriptions of items] area. So, you have to carefully consider what exactly indicates the pain behaviour of the patient. So...I think the BPS is not easy for rating patient pain because you need to take time to think about which description is suitable. The CPOT is better in that you can directly match an action or expression of the patient with a specific description and score on the pain scale, and it can be done quickly. That is why we prefer the CPOT.'*

PN1, FG1: *'At the beginning, it may feel like it [the CPOT] is quite easy to use...but...a few months later, you will find that it is difficult to differentiate between the points on the subscales...after all...sometimes, all you get are 0, so, Ah, no need to look, it's the same, no zone difference.'*

PN2, FG1: *'Ah, at first when you use it, it is not quick, but after more than a month...I think it is the most specific and the most likely to assess the patient's pain score. But then, after more than six months of repeated clinical use, I think it doesn't deserve so much praise...'*

In contrast to the BPS, the PNs outlined more disadvantages and fewer advantages related to applying the CPOT for pain assessment. The following

quotation reveals the PNs' thoughts when comparing the BPS to the CPOT in reference to their role as the raters in their practices. Five PNs across two FGs shared the same thoughts with regards to the use of the BPS and CPOT in ICUs. They indicated that, although the time taken to complete the tasks was reasonable, the CPOT did not give explicit instructions to allow for differentiation between the pain scores. As such, the PNs needed to pay closer attention and take longer to confirm the patient's pain score. They suggested that it might be better to develop a new pain scale, which combined the individual strengths of both the BPS and CPOT:

PN1, FG2: *'I spend more time double checking...Although the CPOT has detailed descriptions; it requires us to double check and recall whether the behaviour of the patient matches the description of the items in the CPOT. Therefore, there may be an error or a difference due to re-assessment. Otherwise, the descriptions of the BPS are succinct and clear enough to allow us to quickly score the patient's pain.'*

PN2 FG 2: *'If you use the CPOT, you will need to think about how to score the patient's pain...It means that the scores you give to indicate the patient's pain can be different before and after you have thought about it. However, you can very quickly assess the level of pain of the patient if you use the BPS. In this sense, I think it is more specific. The perception of the patient's pain may be different after your thinking process.'*

PN1, FG1: *'For example, I think that item descriptions of the CPOT are more detailed than others. It would be better if the CPOT could be combined into the BPS. I mean the CPOT...its subscales, such as muscle tension and body movements, they are very similar. Additionally, the distinctions between their scores are not outstandingly clear, but the BPS provides clear scoring. They should be able to combine their strengths together to...'*

PN1, FG1: *'...Plus the CPOT is described in the BPS...the BPS's layered*

narrative is clearer...so that score would be clearer. In fact, I think that you can combine the two (the BPS and CPOT) into one scale.'

The PNs were asked what kind of comparisons they would make of the three pain scales for use in ICU practice. Although the FPRS is commonly used in current clinical practice, after working with both the BPS and CPOT, the PNs reported that the FPRS, by comparison, did not appear to be sufficiently valid or reliable. The collective opinion of the FPRS remained that it was easy to use; however, by comparison, their objective understanding of a patient's pain was not increased. The CPOT and BPS allowed for both a deeper appreciation of the pain experience from the patient perspective, as well as improved pain treatment management planning:

PN1, FG1: *'...the FPRS is straightforward, but its accuracy is questionable...'*

PN1, FG3: *'...he FPRS can be considered the most common in use, should be counted the most acclaimed, but [laughs]...I feel that it is very easy to observe, then it is also very direct...[sarcasm].'*

PN1, FG2: *'The FPRS is a relatively less....specific evaluation in assessing a patient's pain...Yes, the scores of the FPRS may largely deviate from the actual level of the patient's pain if the patient shows many facial expressions but very limited limb movement.'*

PN2, FG2: *'that one [she held up the BPS documents] is easier for everyone to use. Between the BPS and FPRS, I prefer this [she pointed at the BPS documents]. I think the FPRS is less effective than the BPS. This [the BPS] is simpler than the others because I can immediately grade the patient's pain when I see him. I can quickly assess the level of pain of the patient. Is he/she really in severe pain? As a result, I can easily make a decision about what*

treatment should be given regarding his/her pain. I also think other clinicians [doctors] will prefer to use the BPS for pain assessment.'

PN2, FG2: *'...you can very quickly assess the level of pain of the patient if you use the BPS.'*

Based on their experience, the PNs in the ICU team expressed the opinion that the BPS is the superior scale and provides a specific and valid review for pain assessment. Consequently, its contribution may assist with making more accurate decisions regarding pain management. The BPS can aid the decision-making process of physicians and other care providers within health care in the future. Of note, the PNs stated the importance of cooperation between the attending clinical physician and the clinical nurses:

PN1, FG2: *'This is because I have worked in a surgical department, and know that surgical physicians usually only spend a short time visiting patients. They often quickly look at their patients' pain score [she indicated the FPRS] and leave. They may skip the complicated descriptions the CPOT has or refuse to use it because of the complicated descriptions. Physicians and clinical nurses need an explicit and simple pain measurement method to discuss their patients' pain in order to provide an appropriate prescription...In my opinion, the BPS is a useful tool in clinical practice.'*

The PNs focused on the need for collaboration between themselves and the physicians in clinical practice. It is necessary to create a consistent, mutually agreed upon method for sharing medical records amongst health care providers. This communication is essential in order to make accurate assessments and provide informed, effective care.

6.4.2.9 Suggestion to integrate the respective strengths of the BPS and CPOT

The development and use of the BPS and CPOT, although apparently quite similar, are in fact quite different. The subscales are substantially different enough to make their ease of use a question of accuracy and lost time for PNs. Upon reflection, during the FGs, the PNs had the opportunity to compare and contrast the BPS, CPOT, and FPRS. Based on the scales' respective strengths and weaknesses, it may be possible to refine the current pain measurement scale while redeveloping it. The majority of the PNs expressed the view that a combination of the respective strengths of the BPS and CPOT might result in a more valid and reliable pain assessment scale for NVCPs in ICUs:

PN1, FG 1: *'I would suggest that a new scale can use the description of the breakdown scores explained in the CPOT on the BPS. I mean that the new instrument can be based on BPS grading and apply the items' descriptions of the CPOT to represent different pain behaviour for each score...so the scores would be clearer. In fact, you can combine them (BPS and CPOT) into a scale...'*

PN1, FG1: *'It seems better if the CPOT can be combined into the BPS. I mean the CPOT...its subscales, such as muscle tension and body movements, they are very similar. Additionally, distinctions between their points are not outstanding or clear, but the BPS provides clearer grading. They should be able to combine their strength together...'*

PN2, FG1: *'I feel that in fact, the merger of these two [the BPS and CPOT]...it seems relatively easy to...it would help me determine a more accurate pain score for patients...'*

The PNs expressed the view that the BPS was useless for unconscious patients who were not on mechanical ventilation. The BPS includes an evaluation of “Compliance with mechanical ventilation” and this is not necessarily accurate for all NVCPs in ICUs:

PN1, FG1: *‘... the BPS seems to be only used in patients with intubated ventilation...but if the patient does not need to be intubated...some patients you know...such as those who had tracheostomies but may not be on mechanical ventilation...implementing the assessment of the cough compliance with ventilation seems an inappropriate use of it...I say, if you want to generally apply this scale to each patient in the whole hospital, it means we need to look at it and make a subjective assessment after the cough condition, so it [the BPS] is recommended for patients who are on mechanical ventilation in the ICU.’*

When the focus of inquiry turned to the CPOT and its usefulness when working with patients, the FGs stated that it can be used for non-intubated patients who are able to vocalize. The CPOT “compliance with the ventilator or vocalization” subscale includes a section of two behavioural categories with three pain intensity descriptions. These categories make it possible for PNs to focus on pain behaviour as well as vocalizations to score pain. Due to the specificity of the subscale, PNs are able to choose the most appropriate criteria for assessing patients’ pain, whether intubated or extubated:

PN1, FG3: *‘I think the last sub-item of the CPOT is what we have just talked about - compatibility with the ventilator; it has another option for extubated*

patients, like what a cry or a sigh or something signifies ...I think this may...be more widely used in the intensive care unit, and can be used in patients not using mechanical ventilation...[The other participants also smiled and nodded in agreement].'

PN1, FG1: *'With examples like aphasia, where the patient does not have the ability to express himself, then I think it [the CPOT] can provide some finely tuned information, or instances where patients are in too much pain to report it, and are speechless where a detailed description might otherwise provide some ideas.'*

PN2, FG1: *'These two [the BPS and CPOT] may...be combined together. Because I think...these two scales provide incomplete information about pain scores...it feels like only a fraction when I fill them in. I feel that, in fact...the merger...a combination of them would be relatively easy and I would be more certain of the scores I'm going to give...'*

In summary, most of the PNs were satisfied with the application and ease of use of the BPS, albeit several agreed that patient pain assessment required minimal time. The NPNs across the FGs felt that accurate pain assessments during routine procedures had been observed using the BPS. As such, the nine PNs stated that they expected improvements in pain assessment and pain relief within the ICU as a result of using the BPS. By contrast, two PNs in FG3 preferred the CPOT to the BPS, even though they praised the latter for its sufficiently detailed item by item descriptions of pain behaviour. All of the PNs agreed that the FPRS provides insufficient pain assessment for ICU's

patients. When ICU patients are unable to self-report pain, it becomes necessary to require a specific, comprehensive evaluation through the observation of pain indicators. The PNs identified their satisfaction with the feasibility and utility related to the three pain scales. In order to assess NVCPs' pain accurately, it is essential to pay attention to the various and frequent sources of pain (Desbiens 1996, Twycross & Shields 2008). The following section explores the PNs' views regarding the various types of pain behaviour and the sources of pain from their objective experience.

6.5 Summary

The identified experience of 'pain assessment in nursing' is one of the core foci of ICU nurses. The complexity and sensitivity required accurately and effectively to manage pain in ICU patients remains a significant challenge. Through a quantitative analysis of the current pain scales and the qualitative exploration of the scales' users' perspectives, an informed opinion of the strengths and weaknesses of the current scales emerged. The PNs' experience of the clinical utility, feasibility and barriers of these scales underlines the context within which pain measurement is managed.

The results of the quantitative analysis prompted an inquiry from the nurses' perspective which generated qualitative data. The use of FGs throughout Taiwan produced an overall understanding within the Taiwanese context. The qualitative element of the study, as approached from an epistemological perspective, reflects a valid construct. The responses to various questions regarding the efficacy and ease of use of the scales were explored during the FGs. This provides a more complete

understanding within the practical setting, as well as flagging up any potential problems that need to be addressed.

During the FGs with the nurses, the identification of overt pain behaviour was made known. Satisfaction with the use of these pain scales based on their ease of use was also explored. In addition, the strengths and weaknesses of the BPS, CPOT, and FPRS were discussed from the perspective of clinical use and practicality. All of the FGs agreed that it is vital to minimise the time required for patient assessment in the ICU. Although the FPRS is the simplest and easiest scale for rapidly completing a pain evaluation without the presence of objective benchmarks, it was considered the least reliable. The CPOT undoubtedly provides detailed descriptions of each item to help nurses to evaluate clearly observed pain behaviour. However, they all considered it difficult to distinguish between item descriptions and a score of 0 for 2 on the “Body Movement” and “Muscle Tension” subscales. Nurses must be keenly aware of patient behaviour regarding these two item components in order to be in a position to assess accurately and intervene appropriately. Initially, the PNs in FG1 and FG2 stated they thought that the CPOT would be the easiest and the most objective pain assessment scale employed in the study. Their views changed after working with the CPOT in a clinical setting over the intervening months. The nurses in FG3, who had participated in this study for only 5 months at the time of the interview, stated that the CPOT was the best pain assessment scale employed in this study. It emerged in the FG discussions that the feasibility of the CPOT might be affected by the nurses’ familiarisation with the scale. The PNs in FG1 and FG2 agreed that the BPS provides more explicit pain behaviour descriptions of the items as well as better scoring distinction. As such, the BPS

offers caregivers a simple, objective basis on which to make a decision regarding analgesia therapy in the ICU.

ICU Nurses require a pain assessment scale that is easy to use, has clear descriptors for each item on the scale, and takes minimal time to complete. The FPRS is a simple tool for evaluating pain, as it measures only one visible aspect of it. By comparison, the BPS seems to be a more accurate scale for detecting pain in intubated and unconscious patients compared to the CPOT. This is evidenced through the agreement between the PNs. Based on the experience of the PNs in the ICU, it is apparent that redeveloping the current BPS and CPOT will lead to improved efficacy and ease of use.

Chapter 7 Discussion

7.1 Introduction

The present chapter attempts to bring together theory and empirical findings into an integrative view of the practical aspects of assessing pain in ICU patients undergoing sedative and ventilated treatments. First, the empirical results are interpreted within the theoretical perspectives that generated the associated hypotheses and exploratory goals. This interpretation is next summarised in a brief overview of the main findings. The present study is then critiqued considering both its strengths and limitations, which inform potential trajectories for future research. Finally, a brief summary of the main conclusions is presented.

This chapter will briefly discuss the research processes undertaken and address the main and the subsidiary research questions. The research hypotheses are explored in view of the results and significant findings of the research are summarised. The implications of the findings in practice and future research are presented. Due to the complexity of the scales and the nature of the research several phases were required to explore the research question. In order to address the subjective pain experience in an objective manner as accurately as possible, the mixed methods approach was incorporated. The translation, reliability and validity testing of the pain scales were necessary in order to meaningfully incorporate these scales into the research design. The main research question: “Are the Behavioural Pain Scale (BPS), Critical-care Pain Observational Tools (CPOT), and Wong-Baker FACES Pain Rating Scale (FPRS) valid and reliable pain measurements for assessing pain

in NVCPs who are undergoing intensive care?” Four subsidiary questions were further explored through the three phases of the research:

Phase 1 addressed:

RQ1. Can the BPS, CPOT, and FPRS be used to rate pain intensity in NVCPs?

Phase 2 addressed:

RQ2. What are the reliability and validity on the BPS, CPOT, and FPRS when used to rate pain from non-painful to painful stimulus in NVCPs with critical illness?

RQ3. Which of the BPS, CPOT, and FPRS is the most responsive of the measures?

Phase 3 asked:

RQ4. What are the similarities and differences between the BPS, CPOT, and FPRS when used to quantify pain?

RQ5. What is the preferred scale of nurses when assessing NVCPs in clinical practice in the ICUs setting?

Chapters 4 and 5 of this thesis present a complete examination of the translation of the existing pain scales’ and their validity and reliability testing in NVCPs. Here, it is proposed that the pain scales will benefit by being concisely developed and interpreted within clear definitions. These will include and are not limited to validated measures for scoring and synthesizing patients’ psychometric properties

of pain behaviours. It remains extremely important to remember that multiple variables are in causative effect simultaneously. This is necessary to avoid a simplistic overview, which would reduce the understanding of the complex reality of objective pain assessment. Chapter 6 integrates a detailed and qualitative perspective in a methodical framework. This allows for the biased accommodation of PN's experiences when employing the pain scales of interest in this study.

The mixed methods design allows for combined hypothesis testing and hypothesis generation in a single study (Johnson & Onwuegbuzie 2004). This chapter integrates theory and empirical findings from the testing of the three pain scales into a comprehensive view of pain-related behaviour in NVCPs. The empirical results are interpreted within the theoretical perspectives that generated the associated hypotheses and exploratory goals in Chapter 3. This interpretation is then summarised in a brief overview of the main findings from the FGs. The study is then critiqued, considering both its strengths and limitations, which informs the trajectories for future research. Finally, a brief summary of the main conclusions is presented.

7.2 The Behavioural Pain Scale (BPS)

Strong evidence exists to support the validity and reliability of the BPS as this scale has been tested in a variety of ICU settings with NVCPs. In particular, the BPS showed high inter-rater reliability ($r_s=0.98$) and satisfactory internal consistency (Cronbach $\alpha=0.70$). The correlations and weighted kappa scores compare favourably with other studies that validated the BPS (Ahlers et al. 2008, Payen et al. 2001). The validity of the BPS was demonstrated by a significant increase in

BPS scores during painful procedures in NVCPs which were comparable with other BPS studies of patients with critical illness (Ahlers et al. 2008, Aissaoui et al. 2005, Chanques et al. 2009, Chen et al. 2011c, Juarez et al. 2010, Payen et al. 2001, Young et al. 2006).

7.2.1 Reliability

In the seminal work of Nunnally and Bernstein (1994), it was stated that the small number of items on a scale tended to result in low internal consistency. Therefore, some studies claim there it is unnecessary to examine the internal consistency's reliability (Cronbach α) of the BPS (Ahlers et al. 2008, Chen et al. 2011c, Payen et al. 2001). However, based on the paired patient assessments completed in this study, the BPS was found to be a reliable measure of pain, with an acceptable reliability coefficient. In this study, the internal consistency (Cronbach $\alpha=0.70$) of the BPS was high and each subscale reflected the pain score in a balanced manner (coefficients between 0.48 and 0.55). This result is comparable with other BPS studies (Aissaoui et al. 2005, Chanques et al. 2009, Juarez et al. 2010, Young et al. 2006).

Chapter 4 presents the conclusion that most of the paired evaluations were in close agreement 83%-98% across three measures of patients' pain conditions. These were similar to or higher than the inter-rater agreements in Payen et al. (94%) (2001), Aissaoui et al. (89-95%) (2005), Young et al. (36-91%) (2006), Ahlers et al. (81-100%) (2008), Chanques et al. (90-96%) (2009), and Chen et al. (88-100%) (2011). Those which present the high inter-rater agreements also reported the use of two or more evaluators and an extensive evaluator training

period required. The differences across studies may be attributed to training method of the evaluators and the particular pain scale. Of interest, the lower agreement (58-68%) in the study by Juarez et al. (2010) may be explained by the use of more observers (four caregivers, raters) than was the case in other studies (two nurses). The difference of one point on the pain scale scoring between two independent evaluators is reasonable and acceptable. This is supported by the mean value of the painful procedure-induced changes as scored by the BPS of 0.8-0.6. The subscales of the BPS show a significantly high correlation between each item on the BPS. Given that each item is significant and that the Cronbach's α is reduced with the removal of any item on the BPS; all items are necessary and contribute to the overall reliability of this scale. This result is in alignment with other studies which have similarly demonstrated the three subscales strong relationship. The subscales, as they have been selected and designed effectively evaluate the same construct (Aissaoui et al. 2005, Chanques et al. 2009, Juarez et al. 2010, Payen et al. 2001, Young et al. 2006). Each subscale of the BPS was analysed in order to isolate the dominant item. The findings were: compliance with mechanical ventilation ($r=0.83$), followed by facial expression ($r=0.78$) and upper limb movement ($r=0.73$). This finding contradicts evidence from previous studies conducted by Aissaoui et al. (2005) and Prkachin (1992), which shows that the facial expression subscale is the largest contributor to the overall pain assessment rating. Compliance with mechanical ventilation, contributed the highest pain scores in this study. This is not necessarily a surprising finding when the development of the BPS itself is taken into consideration. The compliance with mechanical ventilation was adapted from the COMFORT scale (Payen *et al.*

2001) and focused on intubated critically ill children. This item contributes the most to the pain scores, as this subscale is more responsive to the effects of ETS as the painful procedure. The use of ETS as the painful procedure was questioned for its veracity, as it is not necessarily painful but will induce coughing which will appear as fighting the ventilator. This observation is supported by the PNs as raters and the inconsistency found in the inter-rater reliability in other studies. The Cohen's Kappa coefficients were inconsistent for the 'at rest', non-painful and painful procedures and ranged from 0.73-0.92 on the subscales. These results are moderately consistent with the ranges in the Cohen's Kappa coefficient in the studies by Ahlers et al. (2008) of 0.54-0.80 and Payen et al. (2001) with 0.82-0.94. This difference is greatest when rating the patient's painful procedure. Chanques et al. (2009) shows a range of 0.61-0.78, which is similar to the results in the present study. Possible explanations for the discrepancy with the Payen et al. (2001) and Chanques et al. (2009) studies are the small sample sizes and were performed on non-intubated patients with vocalisation. The "compliance with ventilation" subscale of the initial BPS was changed to "vocalisation" in the revised BPS. This redeveloped BPS is known as BPS-NI and is specific for use in non-intubated patients that can vocalise but may be experiencing delirium or other lack of mental clarity (Chanques et al. 2009). The results for the BPS-NI on inter-rater reliability (Cohen's kappa coefficient=0.89 for the four conditions and 0.82 during painful procedures) are comparable to the Chinese version of the BPS on NVCPs. The Chinese BPS in this study also shows good inter-rater reliability (Cohen's kappa coefficient=0.97 for the four conditions and 0.81 for the painful procedure) with good responsiveness. Of interest is Ahlers et al. (2008)

BPS study which showed a range from 0.54 to 0.80. This particular range is much greater than that of the present study and Chanques et al. (2009). The discrepancy appears likely due to the lack of experience and training of the raters as may be deduced from the methods section of the research. However, the similarity in the results with the BPS-NI and the Chinese BPS are suggestive of the usefulness of the BPS in a broader context when the specific disabilities of the patient population are taken into consideration.

The qualitative phase of this study contributes to the overall consistency of the BPS based on the experience of the PNs. After being trained in the use of the BPS and the assessment protocol required for the research, the PNs reported high satisfaction with using the BPS. Due to the careful design of the subscales and the clarity of the description of the pain behaviours; if any of the subscales indicated a clear observable pain behaviour, the pain score would increase. As such, the PNs were confident that the BPS was able to accurately reflect the true pain experience of their patient. PNs considered it both easy and clear when assessing pain reactions during routine procedures. However, several PNs expressed concern regarding its relative complexity. The main confusion centred around the second subscale which focuses on upper body movement. As many patients are in restraints the BPS will remain inaccurate. PNs reported that often these patients would exhibit lower body movement in response to the painful procedure. It is noted that the ICU nurses stated that pain ratings may be affected by scores measured on upper limbs movement. It was also reported that it was difficult to differentiate between scores in the subscale “upper limbs movement.”

The qualitative data provides a greater insight into these perceptions and highlights a weakness in the scale design.

These qualitative findings support the findings of Payen et al. study (2001) regarding satisfaction of the nursing care staff working with the BPS. Further, the qualitative component of this study remains consistent with the quantitative approach which shows that the three subscales of the BPS are strongly related to each other.

7.2.2 Validity

The research null hypothesis 1 is within the acceptable range of the psychometric test results. The BPS is a valid tool for assessing pain in NVCPs. There was a significant change in score after the painful stimulus when scoring pain using the BPS. In Group R (the reliability group), the mean BPS score at rest was lower (3.18) than eye care (4.05) or ETS (5.85). However, the SD (1.2) suggests variability in the scores during ETS. Similar findings also emerged for the NVCPs of group A (using the BPS) in Group V (the validity group). Additional tests to compare changes in scores between at rest and non-painful (1.33) or painful stimulus (3.81) showed a significant change using the BPS. Previous studies have shown a similar discriminative validity of the BPS (Aissaoui et al. 2005, Chanques et al. 2009, Chen et al. 2011c, Juarez et al. 2010, Payen et al. 2001, Young et al. 2006). These studies demonstrated that the mean value increased significantly from non-painful to painful situations. The criterion validity is further supported as the pain scores using FPRS are mirrored in the

BPS score. This phenomenon is paralleled with the Numerical Rating Scale (NRS) (Ahlers et al. 2008) and the Non-Verbal Pain Scale (NVPS).

The results from this study revealed that the mean value rose significantly from 3.18 'at rest' to 5.85 during ETS. Changes in BPS scores were also seen in previous studies, with the mean pain score ranging from 3.0 at rest to 4.9 during ETS (Payen et al. 2001). A similar range in pain was found for repositioning. The 'at rest score' was 3.4 and post repositioning was 5.0. Patient turning, scored similarly with 3.73 at rest and 5.41 post turn (Young et al. 2006). A comparable discriminative validity of the BPS was reported by Aissaoui and colleagues (2005). They reported an average BPS score for 'at rest' of 3.9 and 6.8 with ETS and peripheral venous cannulation. This further complements the current study and previous studies (Aissaoui et al. 2005, Payen et al. 2001, Young et al. 2006). Acceptable test results for construct validity of the BPS were obtained in the above studies; however they were done in the same patient group with the same context, which might weaken their validity from a wider perspective. The higher score found by the study of Aissaoui and colleagues (2005) were attributed to insufficient amount of analgesic infusion. The present study resulted in moderately lower scores which may be due to cultural expectations with respect to pain. The patient population recruited are ethnic Chinese with the majority of males represented (67%). Chen et al. (2008) commented that ethnic Chinese patients may believe that pain should be endured and accepted as a process born of fate. In addition, Alabas et al. (2012) stated that men can tolerate pain better than women and tend to be passive in expressing their emotions in public. The scores may have been higher if the pain assessments had been conducted on

women or on people from different cultures. Specifically, the BPS consistently identified changes in pain scores during the ETS and non-significant shifts in pain scores after the non-painful eye care procedure. The greatest increases in pain scores on the BPS were the result of changes in facial expression. These findings are consistent with those reported by Aissaoui et al. (2005), Chanques et al. (2009), Chen et al. (2011), Juarez et al. (2010), Payen et al. (2001), and Young et al. (2006). These studies reported significant increases in the BPS scores when painful procedures, such as turns, peripheral venous cannulation or ETS were performed.

Concurrent validity shows that each tool is theoretically testing the same measure and if so, the scores should correlate with each other (Bannigan & Watson 2009). This study showed the correlation between scores of the BPS and FPRS with some differences. The score correlations at rest (0.66) were stronger than those during eye care (0.59) or ETS (0.47) ($p < 0.001$, $n = 68$). The lower correlation of the BPS and FPRS scores during the painful procedure would appear at odds due to the discriminative validity which is consistent across multiple studies. However, when examining the qualitative data from this study, it appears to be related to expectations of the PNs with respect to the various observable pain behaviours. As the PNs were experienced in the ICU setting with several years, it was noted that NVCPs did not always express pain via facial expression. The weak correlation of the BPS and FPRS scores during the painful procedure may be due to this phenomenon.

On the basis of these qualitative insights, it is not unreasonable to suggest that the BPS subscales allow for improved assessment of patient pain. The study of Ahlers and colleagues (2005) reported a moderate positive correlation between the NRS and BPS during non-painful procedures. This result may be explained by the fact that both the NRS and FPRS include one item for assessing the patient's pain level. This is inconsistent with the current study, yet may be related to the fact that the FPRS and NRS rely on only one indicator (facial expression). By contrast, Juarez's research team (2010) concluded that the correlation between the BPS and NVPS is strong, with a lower correlation at rest. This result is in alignment with the current study and may be due to the NVPS including: 1) Facial expression, 2) Activity (movement) and 3) Respiratory (compliance with ventilator) subscales. These subscales are similar if not the same in the BPS, albeit the scoring method ranges from 0 to 2. The strength of correlation between scales appears to increase when similar subscales are part of the design. Another explanation for the difference in the correlation of the BPS to the FPRS may be related to the data that was used in the analysis. Previous studies mentioned, relied on the actual pain score as observed, whereas the current study focused on the difference between scores. In addition, the two small studies by Chanques et al. (2009) and Chen et al. (2011) were completed with a homogeneous patient group. By contrast, this research was conducted in different ICUs with a larger demographic range and diversity of medical diagnosis within the adult groups. The qualitative element of this study, addressed PNs in relation to management of a patient's pain and their preference of scale. One theme clearly emerged, which was based on the ease of use of the scale. This opinion was shared by all

FGs. Understanding the PNs perspective, explains their preference for the BPS, due to its use and practical application in the ICU setting. The PNs stated that accurate patient assessment required minimal time and allowed for effective pain management during routine procedures. Unanimously the PNs stated that they anticipated improvement in pain assessment and pain relief treatment within the ICU as a result of using the BPS.

7.3 The Critical-care Pain Observational Tool (CPOT)

CPOT studies provide evidence which supports its validity and reliability as it has been tested on NVCPs in multiple ICU settings. The CPOT showed a high inter-rater reliability ($r_s=0.93$) and a satisfactory internal consistency (Cronbach $\alpha=0.821$). The weighted kappa scores and correlations compare well with other validation studies for the CPOT (Vazquez et al. 2011, Marmo & Fowler 2010). CPOT validity was demonstrated by a significant increase in scores of NVCPs during painful procedures and corresponded with other CPOT studies of critically ill patients (Ge linas et al. 2006, Ge linas & Johnston 2007, Marmo & Fowler 2010, Vazquez et al. 2011, Wibbenmeyer et al. 2011). The following discussion examines in greater depth the CPOT and its utility in the clinical setting.

7.3.1 Reliability

Based on the paired patient assessments that were completed by the two PNs, the CPOT was found to be a reliable measure of pain. The results of this study show a satisfactory internal consistency, with a Cronbach's α of 0.70 at rest, 0.73

during the non-painful procedure, and 0.82 during the painful procedure. Nunnally & Bernstein (1994) argued that the creator of the CPOT did not report the internal consistency of either the English or the French version (Gélinas et al. 2006, Gélinas & Johnston 2007, Gélinas et al. 2011). At present, there are few recent studies reporting the internal consistency of the CPOT. The Marmo and Fowler (2010) study found both CPOT and NVPS were reliable with Cronbach's α at 0.89. Similarly, Wibbenmeyer et al. (2011) reported Cronbach's α ranging from 0.62 to 0.71 in a pain study on burn patients that could verbally communicate. The Cronbach's α difference between the Wibbenmeyer et al. (2011) study and the current study may be explained by the pain scale training received by the PNs. The CPOT appears to be relatively consistent in its capacity to objectively assess pain over a wide range of medical conditions. In addition, a high internal consistency during the painful stimulus indicates that in the presence of pain, if any of the items of the CPOT is removed, the reliability is significantly reduced. The present study indicates all items are useful and contribute to the overall reliability of the CPOT. These quantitative findings are supported and enhanced based on the views of PNs expressed during the FG interviews. The PNs reported that the CPOT is an effective pain assessment scale for rating pain in NVCPs due to its' operational definitions of the levels of pain. To increase internal consistency, several compatible operational definitions are needed (Riketta 2005). The FGs revealed that due to the clarity of the pain definitions, PNs were able to quickly and accurately assess patients' pain. The qualitative data suggests that all of the subscales contribute to the high reliability of the CPOT.

At present in the literature, the inter-item correlations of the CPOT remain unreported, as such, comparisons are impossible. The results of the present study reject the fourth null hypothesis in which there is no relationship between items greater than 0.4. At 0.411, the coefficient of the relationship between facial expression and compliance with mechanical ventilation is not particularly strong. The coefficient of the relationship between muscle tension and compliance with mechanical ventilation is $r_s = 0.705$, $p < 0.01$. This suggests a strong relationship between these two items.

Regarding inter-rater reliability, Gélinas and Johnson (2007) reported that the ICC for the English version of the CPOT ranged between 0.80 and 0.92. Damström et al. (2011) also demonstrated that the Swedish version of the CPOT has strong inter-rater reliability, with an average ICC at 0.84. In another study, the agreement between raters ranged between 80% and 85% (Marmo & Fowler, 2010). These results are comparable with those obtained by the present study for measuring the inter-rater reliability of the CPOT on NVCPs. Further, the average inter-rater agreement at assessment using Spearman's rank correlation coefficient is 0.94. By contrast, the inter-rater reliability of the CPOT, as measured by Wibbenmeyer and colleagues (2011), had a Pearson correlation coefficient of 0.63. The correlation coefficient of 0.63 is low and may not be indicative of the CPOT as this statistic relies on a consistent variable. Pain is not a consistent variable and the incorrect use of statistics may lead to an incorrect conclusion. Another potential reason for the lower correlation in the Wibbenmeyer et al. (2011) study is the use of a burn patient population. These types of patients show reduced movement due to constant pain from the burn and

can cause muscular rigidity. Another meaningful statistic to calculate inter-rater reliability is Cohen's kappa statistic. In the current study, the agreement between raters is reflected in the weighted kappa scores for the Chinese version of the CPOT (0.65 - 1.00 for individual items) and compared favourably with other studies validating the English version of the CPOT. Gélinas et al. (2006) study showed a weighted *k* coefficient ranging from 0.52 to 0.88. Similarly, Vazquez et al. (2011) research on 96 cognitively impaired ICU patients showed a weighted *k* coefficient of 0.79 to 1. In addition, the inter-rater reliability of the CPOT, as measured by the weighted kappa coefficient on burn populations, showed a range of only 0.26 to 0.43 for individual item agreement between assessors from different professions (Wibbenmeyer et al. 2011). The Wibbenmeyer study employed different professionals to assess pain and only briefly educated on the use of the scales and the purpose of the study. This may explain why there was limited cross-professional generalisability of the inter-rater consistency. Vazquez et al. (2011) and Gélinas et al. (2006) showed weighted *k* coefficients that are moderate to high for all assessments and similar results were obtained in the present study. However, only two evaluators used the instrument, which is a limitation when examining inter-rater reliability. These results cannot be generalised to other ICU nurses.

7.3.2 Validity

Based on the quantitative findings, this present study validated the Chinese version of the CPOT. Significant high correlations between the CPOT and FPRS were found indicating good concurrent validity. In addition, The CPOT scores were higher during suctioning (painful procedure) than at rest and during eye

care (non-painful procedure) and addresses null hypothesis 9 of this study. Both the criterion validity and discriminant validity indicate that the Chinese version of the CPOT provides an accurate criterion for measuring pain in NVCPs.

The gold standard for pain assessment is a patient's self-report of pain. In the study by Ge'linas et al.'s (2006), patients' self-report of pain using the Pain Intensity Description Scale to understand the criterion validity of the CPOT was employed. Their study showed that this measurement of pain intensity correlated moderately with the CPOT scores (Pearson correlation coefficient of $\rho=0.40\sim0.59$). A Pearson correlation coefficient was also used to compare the CPOT scores with the patients' self-reported pain scores using the NRS and VAS in another study (Wibbenmeyer et al. 2011). However, the CPOT failed to reflect the patient's pain accurately as reported when the patient completed the VAS or NRS scales (Pearson correlation coefficient of $\rho=0.27\sim0.33$). A small population ($n=38$) within a single ICU was recruited for the study, which may be a limitation in providing sufficient data for examination. In the current study, a Pearson correlation coefficient was used to quantify the ability of the CPOT to measure accurately what it intends to measure. This was accomplished by comparing the CPOT with the FPRS scores during the painful procedure. The CPOT scores were highly correlated with the FPRS with moderate coefficients. The high correlation may be due to the facial pictures of the FPRS being similar to the facial changes described in the CPOT. Of note, the FPRS scores were highly correlated with the CPOT but not with the BPS. This may be related to the theme of "the CPOT was difficult to understand and score" that emerged from the FG interviews. PNs stated that the CPOT provides clear operational definitions of

pain, but scoring was problematic due to the lack of clarity between 0 and 1 pain descriptions.

The present study reports the CPOT scores as having a high correlation with the FPRS (with coefficient $\rho=0.58\sim0.66$). However, potential limitations of the present study need to be considered. The FPRS is not a gold standard instrument for measuring pain. A patient's self-report is considered to be the most reliable measure of pain (McCaffery & Pasero 1999, Prkachin et al. 2007b). To improve the data of the present study a verbal report of pain to evaluate the criterion validity of the BPS and CPOT would be useful. Another study similarly lacking patient self-report of pain is that by Damström et al. (2011), which relied on physiological indicators to assess the criterion validity of the CPOT. They reported that the criterion validity of the CPOT correlated with vital signs at $\rho=0.32\sim0.45$. However, these patients received both sedation and analgesia, which would confound the physiological indicators of the patients' pain.

The subscales of the CPOT showed statistically significant correlations with correlation coefficients above 0.5. (Table 5.9) In accordance with expectations, the study demonstrates confidence that the concurrent validities between domains of the CPOT are genuine. However, the CPOT subscales "Compliance with mechanical ventilation" and "Facial expression" shows evidence for divergent validity, as the correlation was only 0.08 ($p>0.01$) when patients received the non-painful procedure. This point may be addressed by the findings of the qualitative data from the FGs in this study. The PNs stated that although the CPOT has detailed descriptions, they needed to double check and recall the

patients' behaviour in order to match the description of the items when scoring pain using the scale. The risk of error or a difference due to re-assessment is a strong probability. In particular, when using the CPOT, distinguishing the difference between point 0 and 1 was problematic. PNs in this study indicated that using facial expressions to measure pain is a subjective form of pain assessment that might easily lead to divergent measurements due to the varied experience of the nurses or differing personalities of the patients.

Discriminant validity was supported by the higher CPOT scores during the suction procedure than at rest and during the eye care procedure. The changes in the CPOT scores in participating patients were significantly higher than the rest score during both the non-painful and painful procedures. The level of fluctuation in CPOT scores between at rest and during the painful procedure was statistically significant and higher than in patients who underwent the non-painful procedure. The results of this study support the clinical recommendations of multiple studies in which the CPOT is considered a valid indicator for pain assessment (Chen et al. 2011b, Gélinas et al. 2006, Gélinas & Johnston 2007, Gélinas et al. 2011, Nürnberg Damström et al. 2011, Vazquez et al. 2011, Wibbenmeyer et al. 2011). Acceptable test results for the construct validity of the CPOT were obtained by the present and these previous studies. However, validity testing of the CPOT is required to be performed with different patient groups, different contexts, and different languages, as validity testing is an on-going process (DeVellis 2011). Previous studies relied on smaller population numbers and were completed within a homogeneous patient group. This prospective study was conducted with

various ICUs and in multiple adult groups. The results of the present study may be more useful in addressing the hypothesis.

7.4 The Facial Pain Rating Scale (FPRS)

Face scales are frequently used as self-report measures of pain intensity in clinical practice. In the systemic review of face scales for pain in children by Tomlinson et al. (2010), the FPRS was shown to be the most widely used and best validated facial pain scale. The FPRS scores in this study were internally consistent and showed good discriminatory power in the patient population. The results are comparable with those obtained by previous studies in terms of reliability and validity.

7.4.1 Reliability

The FPRS relies on only one item for the measurement of pain intensity. Therefore, an internal consistency estimate of the reliability of the test scores cannot be employed to test the FPRS. For a reliability estimate of the FPRS, inter-rater reliability was used to assess the degree of agreement between two or more raters. Previous studies identified that there was moderately strong agreement regarding the use of the FPRS between children and parents, with $r=0.79$ (Badr Zahr *et al.* 2006) and $r=0.46$ (Hay et al. 2009), or no significant difference in FPRS scores between evaluations by parents and children ($p=0.11$) (Rajasagaram et al. 2009). In Group R (the reliability group), this study also found that there was no significant difference between the FPRS scores assessed by the two raters. There was a moderately high degree of agreement between scoring at rest, during non-painful and painful procedures ($p=0.775$ to $p=0.819$). The resulting inter-rater reliability was supported by moderate weighted k coefficients with 0.54 at

rest and 0.45 during the painful procedure. However, this study obtained a low weighted k coefficient of 0.37 when the researcher compared the FPRS scores between the two PNs during patients' eye care (non-painful procedure). This may be explained by the fact that using a cotton swabs on the eyelids probably induces frowning during the eye care procedure which consequently affects the facial expression of the patients. Scores related to facial expression were higher in patients while an eye care procedure was being performed on them. This finding provides valuable information about how this factor can confound pain scores for patients who are undergoing simple routine care procedures. The low inter-rater reliability of the FPRS in the present study may in part be explained by the qualitative findings. As described in the previous section, the PNs reported that completion of the FPRS was simple. The FPRS makes a visual equation of a patient's pain using the single domain of facial expressions. However, based on the present study and others, the FPRS may not be suitable for many patient populations.

7.4.2 Validity

The FPRS scores were higher during the painful procedure, lending support to its validity. The mean value and standard deviation for the painful procedure in this study population was comparable with other FPRS studies on child patients. (Tomlinson et al. 2010) During the painful procedure there was a significant increase in the FPRS scores compared with those for patients at rest. This provides support for the discriminative validity of the FPRS. However the standard deviation of the painful procedure in the present study ($SD=1.36-1.41$) was considerably smaller than in other studies (Badr Zahr et al. 2006, Cohen et

al. 2007, Hay et al. 2009, West et al. 1994). Nurses' pain intensity scores of children are usually significantly lower than the scores of the parents and the childrens' self-report (Rajasagaram et al. 2009). By comparison, in the present study, the pain ratings were scored only by nurses which may act to bias the results. The expected positive relationships found between the FPRS and measures of the BPS and CPOT provide additional support for the concurrent validity of the FPRS. These results are consistent with those described by Chambers (2005), where a strong relationship between the FPRS and the other four pain scales for children's self-report was assessed. Similarly, correlation of the FPRS with Poker Chip Tool invented by Hester was also moderately strong for children's pain assessment in West's (1994) study. The FPRS may be acceptable based on consistent findings that there are significant correlations exists with other scales, however, the values of the correlation coefficients show a wide range. The magnitude of the range in the correlations between the FPRS and different scales when used for both adults and children suggests further investigation. The confounding of emotion with pain intensity in the representation of the faces is a major concern with the FPRS. Children who cry easily when in pain, especially younger children, may easily express a painful facial expression. This will result in higher scores using the FPRS as only facial expression is scored. As a result, the possibility of overestimation of pain scores using a single dimension pain scale will not be optimal.

7.5 Comparison between BPS, CPOT, and FPRS

This study confirms that the BPS, CPOT, and FPRS all display good metric properties amongst NVCPs in Taiwan. The ability to accurately discriminate pain

intensity between known painful and non-painful procedures with high reliability was found using BPS, CPOT and FPRS. The quantitative results support the adequacy of these three scales for measuring pain intensity in patients who are unable to self-report their pain. Psychometric analysis assesses a scale's effectiveness based on its reliability, validity, and responsiveness. However, researching the subjective experience while relying on a quantitative approach may remain fundamentally misleading (Johnson & Onwuegbuzie 2004). The following section will encompass the findings from the FG interviews to expand on the understanding of the feasibility and clinical utility of the three pain scales. The first section compared the reliability of the BPS, CPOT, and FPRS to analyse the ability of each scale to score pain across observers, subjects, and sub-items on a scale. In addition to reliability, the scales must also show criterion validity. Criterion validity is analysed by comparing a scale's performance with that of a gold standard instrument. The current study employed the FPRS as the comparator. The following section provides a comparison of the scales and the responsiveness of each scale for scoring pain intensity. The discussion will conclude with a description of the PNs evaluations of the feasibility and clinical utility of the three pain scales in assessing pain in NVCPs.

7.5.1 Reliability

Based on the findings of the present study, the BPS, CPOT, and FPRS were acceptable in terms of reliability and validity in assessing pain in NVCPs. The FPRS revealed a slightly lower relationship of inter-rater correlation between the two raters' responses than was found for the BPS and CPOT. The inter-rater agreements between two raters for the FPRS using the Cohen's kappa coefficient

also appeared fair during administration of at rest or non-painful and painful procedures.

The Cronbach's α is based on the inter-item correlations; however the number of items is also relevant to the outcome. The greater the number of items, the higher Cronbach's α , similarly, if the average inter-item correlation is low the Cronbach's α will decrease (DeVellis 2011, Mohsen & Reg 2011). In this study, both the number of items and the average inter-item correlations are important. The CPOT, with the most items (4), has Cronbach's $\alpha=0.821$, and the inter-item correlation average is only 0.536. The average inter-item correlation of the BPS is lower at 0.439, and subsequently the Cronbach's $\alpha=0.700$. This might be because the BPS contains fewer items than the CPOT. The FPRS has only one item, as such, no correlations between different items on the same test is possible. The three pain scales all exhibit a high internal consistency. An important finding in this study is the high inter-rater agreement using a Spearman's rank correlation for the BPS ($\rho=0.83-0.98$) and CPOT ($\rho=0.90-0.98$) and FPRS ($\rho=0.78-0.82$). Of note is the reduced inter-rater agreement for the FPRS, which may be due to the reliance on only one pain indicator. The potential for objective bias cannot be ignored nor calculated. By subtle contrast, the Spearman's correlation was stronger for both the CPOT and BPS and may potentially be explained due to the clarity of the objective item description. Direct comparisons between this study and other research remains difficult to inconclusive as the study design is a primary consideration. The Marmo & Fowler (2010) study found the correlations between evaluators were moderate to high for the CPOT and NVPS. Similarly the multi-item CPOT showed a stronger inter-rater correlation in the present

study. The current study also supports the Marmo & Fowler (2010) results in that disagreement between raters was most common when rating the facial expression component for BPS and CPOT. This discrepancy was particularly prominent when rating pain during the procedures. Of note, the Cohen's kappa, which focuses on each item on the scale for the two raters showed similar ranges. The Cohen's kappa range for BPS is $k=0.73-1.00$ and the CPOT is $k=0.65-1.00$. These are both much greater than that for the FPRS range of $k=0.37-0.54$. Marked disagreement between raters was evident in the "facial expression" item for both BPS and CPOT. Similarly, the FPRS with the single item component did not score greater agreement. The disparity in the facial expression scores is difficult to accurately calculate due to the variation in the scoring method for each scale. (BPS=1, 2, 3, 4, CPOT=0, 1, 2, and FPRS=0 to 10). The item with greatest disagreement remains the "muscle tension" component of the CPOT during the painful procedure. The disagreement in inter-rater reliability scores may be explained due to the influence of several factors: 1) number of items comprising the scales, 2) objectivity of the scoring (Colton et al. 1997). Reliability increases as the number of items increases, as such; the inter-rater reliability of the FPRS was the lowest in Group R. This remained the case regardless the diagnosis of the patients, as the FPRS relies on only a single item subscale to measure pain intensity. Objectivity of a test may be assumed if all users arrive at the same score. The proper training of raters followed by the proper monitoring of their scoring can produce evaluations which approach total objectivity (Bresciani et al. 2009). In this study, the two PNs (nurses) had been trained in the use of the three scales to score patients' discomfort at the same time. The FPRS is commonly used in

hospitals in Taiwan, and none of the PNs had used the BPS or the CPOT previously. Clearly, the PNs were more familiar with the FPRS than either the BPS or the CPOT. As such, they were cautious about adopting the BPS and CPOT. In order to increase the accuracy of objectively scoring pain, an increase in the number of categories for observing pain behaviours must be part of the pain scale design. Although the CPOT contains more than one pain behaviour item, it has fewer response levels to score. This may result in data from the Likert format rated items becoming significantly less accurate as the number of scale points drop (Johns 2005).

The quantitative result in phase 2 supports the reliability of the CPOT and BPS as does the data obtained from the qualitative FG interviews. Nine of the PNs indicated that the FPRS is a subjective tool and that there is a clear difference between the raters scores. They concluded that the BPS and CPOT would be more accurate in its ability to assess pain compared to the FPRS. The category “muscle tension” in the CPOT was described as the most confusing pain behaviour to gauge. This item subsequently had the lowest k coefficient during the painful procedure. Not only was there confusion in the scoring of the behaviour, but there was also uncertainty as to the difference between the categories of “muscle tension” and “body movement”. Currently, the poor correlation between the two PNs ratings using the CPOT may be explained by the difficulty to simply observe muscle tension. Then, assuming that the correct behaviour is being observed, assigning a meaningful score becomes a challenge. In this category, “tense” and “rigid” were rated as 1, and to receive a score of 2 a patient must be observed to be “very” tense or rigid. PNs in the interview stated

that it is uncertain about how they ought to define and differentiate “tense” and “rigid”, or quantify these terms compared with “very tense” and “very rigid”.

7.5.2 Validity

Comparison of the changes in patients’ pain levels in a set of rest and painful and non-painful procedures showed significantly different results amongst the three scales’ groups. Pain scores assessed by pain scales are ordinal data and are less sensitive to outliers than when using parametric methods. The Wilcoxon signed rank tests were used to analyse the distribution when ties are present. The Wilcoxon signed rank test shows that procedures used in this study elicited statistically significant changes in pain scores when using the BPS, CPOT, and FPRS to assess pain (Table 5.16). This test provides interesting data on the comparison of the participants’ pain scores for patients’ pain before and after the non-painful eye care regimen. The majority of the NVCPs made no change in the pain score for the FPRS group compared to the BPS and CPOT groups. There were no tied observations, in which the pain scores obtained from before and during a painful procedure have the same value in all three scale groups. This might be explained by the comments regarding use of the FPRS made by the PNs in the focus group. PNs stated that the facial expression score may be biased if the patient generally exhibits frowning and brow lowering behaviours.

In light of the discussion of each scale in the previous section, the current research supports the many previous studies that found significant changes in the pain scores between different procedures experienced by patients on all three scales: the BPS (Aissaoui et al. 2005, Chanques et al. 2009, Chen et al. 2011c,

Juarez et al. 2010, Payen et al. 2001, Young et al. 2006), CPOT (Damströ M et al. 2011, Gélinas et al. 2006, Gélinas & Johnston 2007, Gélinas et al. 2011, Vazquez et al. 2011, Wibbenmeyer et al. 2011), and FPRS (Tomlinson et al. 2010). Those patients who suffered severe pain from a painful procedure (endotracheal suction) reported higher pain scores than those who were scored while at rest or during a non-painful procedure (eye care). A follow up study was conducted to examine the difference in the pain intensity levels of changes in Group V (the validity group) using the ANOVA test. The changes in the mean scores for the BPS group did not significantly differ between at rest and during the painful procedure in this study. This result is problematic as it contradicts most other research. In particular, the Group R, showed a lower coefficient during the painful procedure than when at rest between the BPS and FPRS. This reduced correlation coefficient may be attributed to the difficulties experienced by the PNs when assessing pain using the BPS. The PNs indicated that the BPS use the category of “upper limbs movement” may lead to underestimation of pain when patients are in protective physical restraints.

The criterion validity of the BPS and CPOT compared with the FPRS shows an expected positive relationship. The CPOT shows a slightly stronger correlation with the FPRS than the BPS. In Section 6.4.2.6, it is suggested that using the single component of facial expression to measure pain in NVCPs may result in extremely inaccurate the pain scores for this particular population. The FPRS with the single item of “facial expression” is sub-optimal when compared to the BPS and CPOT for assessing pain in ICU NVCPs. In spite of Prkachin (1992) providing that evidence for a universal facial expression of pain, the findings

from the current study indicate that the PNs would underestimate or overestimate patient' pain due to factors like the personality of the patients, culture and the environment (Pieh et al. 2012, Tsai 2007, Turk & Okifuji 1999). From the qualitative data, the PNs believed that pain scores between the BPS or CPOT and FPRS in the non-painful procedure would be more different in the painful procedure.

Due to the subjectivity of rating “facial expression” for pain intensity, concerns remain for the confounding effect of emotions. As a result, it is suggested that the CPOT and BPS may be more appropriate than the FPRS. The following section delves into the effect size coefficients of the BPS, CPOT, and FPRS as well as responsiveness to changes in pain before and during a procedure.

7.5.3 Responsiveness between regimes

The coefficient of effect size is the ability to detect an important relationship between the treatment effect and the variability in response (Norman et al. 2007). This was used to verify the capacity of the BPS, CPOT, and FPRS to discriminate pain and provide sufficient evidence that these scales are valid instruments. Table 5.13 shows that the BPS, CPOT, and FPRS' total and subscale scores were significantly higher during the painful procedure than the non-painful one. The patients in the Group V were randomly assigned to three groups using the three pain scales. Coefficients of change for each regimen were high for all categories of all three scales. The findings imply that these scales are sufficiently responsive for detecting patient pain. However, the BPS responsiveness to change in the present study was lower than in the studies of Aissaoui and colleagues (2005)

and Chanques et al. (2009). This may be due to the study design, such as the procedures chosen and small sample size. Excellent responsiveness was recorded from 38 patients in the Aissaoui et al.'s (2005) study while at rest and during the painful procedures: tracheal suction and peripheral venous cannulation. Chanques et al. (2009), meanwhile, tested the BPS on 30 patients, using dressing change of venous catheter and turning as the painful procedures. The current study evaluated the BPS, CPOT, and FPRS during both a non-painful procedure (eye care) and a painful procedure (tracheal suction) to analyse their responsiveness. The reduction in responsiveness in this study is indicative of the patient population and not the skill of the raters use of the pain scales. Eye care is a regimen which is known to cause mild discomfort or be considered a non-painful stimulus; however the responsiveness of the scales suggests the opposite. The lower coefficients may yet be explained based on the factors that were analysed. The Chanques et al. (2009) and Aissaoui and colleagues (2005) the coefficients were calculated by the difference between the mean scores while at rest and during painful procedures. By contrast, the coefficients in the present study were calculated by changes in the mean scores calculated during rest and during non-painful and painful procedures. Due to the paucity of research regarding the responsiveness of the CPOT and FPRS these two scales may not be comparatively discussed based on the current study.

The current study is the only known research into the responsiveness of the BPS, CPOT, and FPRS. This remarkable deficit in the research of pain intensity is significant, as one of the most important aspects to accurately evaluate a patient's pain experience is not present. Raters are able to detect differences in pain

intensity between clinical regimens using the BPS, CPOT, and FPRS. NVCPs receiving a painful procedure scored higher pain scores than those receiving non-painful one. The greatest effect size was found using the BPS ($ES = 2.5$), followed by the FPRS ($ES = 2.2$) and the CPOT ($ES = 1.6$). These results exhibit the ability of all three scales to quantify change in pain intensity under different stimuli. The BPS exhibited the best responsiveness, suggesting that it has good ability to detect the impact of painful stimulation in NVCPs. Unexpectedly, the ES coefficient of the CPOT was lower than in the FPRS. This may due to the PNs lack of familiarity and relatively short term use with these scales. (Juarez et al. 2010). This phenomenon may explain the reduced ability of the CPOT to detect important changes over time as compared to the FPRS. The qualitative results, based on the PNs statements, reflect the quantitative and the lower ES of the CPOT as compared to the BPS and FPRS. A similar result using the CPOT was found in a previous study comparing the psychometric properties of the NVPS and the CPOT (Marmo & Fowler 2010). This result is reflected in the present study and the potential reasons for the reduced ES have been discussed in section 6.4.2.4. The preliminary results have demonstrated that the BPS, CPOT, and FPRS are reliable clinical assessment tools with satisfactory construct validity for pain measurement in Taiwanese's NVCP with acute pain. The exploration of each category of the three pain assessment scales in detail will be addressed in the following sections.

7.5.4 The clinical utility of each scale

The data from the three FGs explores the feasibility and clinical utility of the BPS, CPOT, and FPRS. Direct comparisons of this present study with other

studies remains challenging. As such, some of the verbatim findings from the FG interviews have been included to compare with those from previous studies.

The ES of the BPS, CPOT, and FPRS show that the three scales had an excellent ability to quantify change in pain status and detect a painful stimulus. Based on the ES for the BPS of ES=2.5, it can be concluded that the BPS remained the best pain scale in the target patient population. Similarly, the views expressed by the FGs showed that PNs exhibited a preference for the BPS. In examining FGs with PNs, multiple issues were exposed regarding the use of the BPS, CPOT and FPRS. The following summarises the strengths and weaknesses related to the use of each of the three scales with NVCPs in the ICU setting.

All FGs agreed that patient assessment in the ICU must be completed within the minimal amount of time. The FPRS is the simplest and easiest tool for rapidly completing a pain evaluation without objective benchmarks. This result supports the findings of a previous study in which the nurses also reported that the FPRS is easy and quick to use and inexpensive to reproduce (Stinson et al. 2006). The inclusion of the FPRS along the side of the vital signs sheet used in the ICU is both convenient and less expensive. The greatest strength of this scale may be its acceptability, given the consistent findings of the present and previous studies (Chambers et al. 2005).

PNs stated that the FPRS is the most subjective pain measurement of the three scales. According to the PNs in the present study, the scale is easily scored on the widely accepted conventional 0-to-10 metric. The FPRS relies on facial expressions and is easy, simple, and quick to use. Inherently, the danger of the

emotional component of a pain depiction may result in affecting the objective perception of the observer when rating pain. These findings are in line with those of previous studies (Chambers & Craig 1998, Taplin et al. 1999). The qualitative findings provide an important insight about the use of picture communication aids to assess pain. One PN stated: “...*I feel that it is very easy to observe, and it is also very direct because it matches pictures to facial expression...*” This result supports the finding of a previous study, where nurses also reported that the FPRS was the easiest, quickest to use as well as the least expensive to reproduce (Stinson et al. 2006). Another PN also stated: “...*I would suggest that a new scale can use the description of the breakdown scores explained in the CPOT and the facial picture of the breakdown explained in the FPRS on the BPS...*” To sum up these findings, this study suggests that a new scale for assessing pain in critical patients with a lack of verbal ability may integrate the strength of the BPS, CPOT, and FPRS.

In line with the satisfaction survey by Payen et al. (2001), the results of the FGs reveal that the BPS was practical and well accepted by the PNs in this study. FG interviews suggest that the BPS was the most useful for measuring pain levels and determining the efficacy of analgesia. The PNs in the present study reported that the BPS required minimal time (three minutes) as per the findings reported by Payen et al. (2001). Given its’ relative complexity, compared to the FPRS, it remained both quick and accurate to employ. Due to the nature of the exploration of the qualitative aspect of the study, the PNs required consensus to define overt expressions of pain. PNs reported that the main three components for NVCPs are: 1) “change in vital signs from baseline”, 2) “facial expression”, and 3) “body

movement”. The BPS includes “facial expression” and “body movement”, albeit body movement is restricted to “upper limb movement.” However, based on the consensus of the PNs and the inclusion of two of the main components in the BPS, this scale was most preferred in the ICU. It can be concluded that the BPS had sound psychometric properties and is useful for scoring pain in NVCPs. The BPS has also been re-developed for use in non-intubated patients in ICUs for NVCPs. Chanques and colleagues (2009) demonstrated that the BPS and the Behavioural Pain Scale-Non Intubated (BPS-NI) are valid, reliable, and responsive instruments for assessing pain in critically ill patients who are unable to self-report.

CPOT undoubtedly provides detailed descriptions of each item to help PNs’ evaluate patients observed pain behaviours. However, PNs considered it difficult to distinguish the difference between item descriptions and the points zero to two on the subscales, “Body Movement” and “Muscle Tension”. PNs need to be keenly aware of patient behaviours regarding the two item components in order to accurately assess and intervene appropriately. These comments by the PNs tally with the results of the study by Marmo and Fowler (2010) study. Initially, the PNs in FG1 and FG2 stated that the CPOT would be the easiest, most objective pain assessment tool. Over the course of the study and using the three pain scales, their opinion changed. The PNs in the FG3, who had been participating in this study for only 5 months when they were interviewed, stated that the CPOT was the best pain assessment tool employed in this study. Through the FG discussions, the understanding that the feasibility of the CPOT may be affected by the PNs’ familiarisation with the instrument emerged. The PNs in

FG1 and FG2, concluded that the BPS provides an explicit grading assessment component of the item descriptions. This includes wording and levels distinction, such that it offers caregivers a clear, objective basis on which to make a decision about analgesia therapy in the ICU.

The qualitative findings suggest that nurses require a pain assessment tool that is easy to use, with clear descriptors for each item, and which requires little time to complete. The FPRS appears to be a simple tool for evaluating pain as it relies solely on facial expression to interpret patient behaviour. The BPS appears to be a better tool for pain detection in intubated and unconscious patients compared to the CPOT, as evidenced by the better agreement between the PN raters. In summation it is suggested that succinct integration of the BPS and CPOT for more accurate scoring would allow for more useful evaluation of pain in ICU NVCPs. Despite the considerable body of literature devoted to self-reported pain assessment, there has been little discussion of behavioural pain assessments for NVCPs with critical illness. The elegance of the mixed methods research approach allows for a comprehensive picture that challenges this lack of information for pain assessment among NVCPs undergoing sedation or mechanical ventilation.

7.6 Study Limitation and Strengths

A lack of scientific rigour reduces the value of many studies that were examined as part of the literature review. Frequent are flaws in the experimental design and subject selection, both of which threaten the validity of the results (Bryman 2008). The location and settings for each study was very different and not directly

comparable to the next. Similarly, the dependent and independent variables were quite different, which results in the inability to generalize the results. Due to the nature of the subject matter under investigation, it is reasonable that such diversity exists in the research available.

Focus groups are an effective method for generating familiarity with the study target. However, this technique also has its limitations when not executed properly. It is important to know the limitations and the advantages of both approaches. The quantitative approach when combined with the qualitative is able to generate more useful data which allows for practical applicability.

7.6.1 Limitations

In the present study, several limitations exist and may have influenced the study outcome. The potential for pre-existing conditions amongst the patient population is a variable for which the selection criteria may not have been effective. As the present study employed both a mixed methods approach as well as several phases the limitations will be examined accordingly. Phase 1 component and subsequent research relies on the translation from English to Chinese of the BPS and CPOT. Neither of these scales was assessed for validity or reliability outside the parameters of the current study. First, limitations are taken into consideration with regard to the study design in the second phase of this present study. Second, a further limitation is that the findings only pertain to a certain set of the individuals in the third phase of the present research.

An important limitation and which cannot be underestimated is the potential for flaw in the original design. This may in part be based on the current research

available, as important factors of the design may not be directly replicated for accurate comparison. These design weaknesses may be in relation to improperly controlled variables or were simply not reported. Each study uses unique procedures and equipment, rendering direct comparisons meaningless. The most important limitation in this study is the lack of a double-blind design. Observers (PNs) could not be blinded to the painful or non-painful procedures as in similar studies (Aissaoui et al. 2005, Chanques et al. 2009, Gélinas et al. 2006, Gélinas & Johnston 2007, Payen et al. 2001, Riker et al. 1999, Sessler et al. 2002). The PNs may have been biased in their assessment of pain behaviours during the painful procedure. To minimise bias and implement a double-blind for rating pain; the observations of two PNs post procedure would allow for potentially more meaningful data. Both the painful and non-painful procedures for pain assessment research if standardised would allow for far greater comparative capacity. From the perspective of research purposes as well as ethical considerations; standardization of painful procedures implemented for pain assessment research purposes could improve the quality of research design. The **sociocultural** component of human research is of known importance and unknown effect. The current study did not delve into the ramifications from this perspective and may affect the outcome of the evaluation of the BPS, CPOT and FPRS. Despite that limitation, the findings obtained for BPS and CPOT remain consistent with those reported in other countries. This suggests that there are commonalities amongst patients in pain, despite different characteristics in other regards. The current findings strongly suggest that the BPS and CPOT are acceptable for use in heterogeneous Chinese patients with acute pain and

clinically applicable. The choice of eye care as the non-painful procedure may have influenced the pain score of the facial component, as cleaning patients' eyes stimulates changes in facial expressions. The responsiveness of the three pain scales was not assessed and may have provided further understanding. However, given similar findings in other studies involving the BPS, CPOT, and FPRS, it is reasonable to suggest that the three instruments show sensitivity to different treatments. The study was designed with nurses as pair observers, which may impose a limitation on cross-professional generalisability of the inter-rater agreement. The lack the gold standard for pain assessment (self-report) may have influenced the primary analysis which aimed at evaluating the criterion validity of the three study instruments. Despite the lack of a self-report component in this study the data remain in alignment with other research for the CPOT. (Gélinas & Johnston 2007) The unexamined relationship between pain scores, medication and the lack of patients' self-assessment is of concern. An important limitation of the present study is the lack of threshold scores of the three pain scales. These scores require the capacity of the patient to self-report and as such were not possible to obtain. This loss of data may reduce the predictive accuracy of the current study. This study was not able to confirm the validity of threshold values of each scale due to a lack of data on verbal reports of pain. This threshold refers to the minimum objective pain score rating when compared to the gold standard of self-report. This remains a fundamental limitation, however the research by Gélinas et al. (2006) and Gélinas & Johnston (2007) are strong indicators that the current study findings are of merit.

The qualitative aspect of the research was limited in scope due to the numbers of PNs that were willing to contribute. Further to which, the limited numbers of PNs reduced both the FGs available and their size. The aim of the FG discussions in this study was to explore PNs experiences working with the three pain assessment tools. These discussions expanded to other topics that PNs linked to their experiences as clinical nurses in the ICU. FGs rely on group dynamics to access shared knowledge of a subject (Marková 2007). In the qualitative approach of this present study, the time limit and geography of the FG meetings did not allow for further exploration into the expanded topic areas. This may be a loss of potential insight into the PN perspective. This was particularly true for PNs from different clinics in an FG who were not familiar with each other. However, previous studies in pain assessment provide insight and analysis into nurses' perspective regarding pain assessment in NVCPs and similar were the findings in the present study. The PNs were willing to participate and readily shared their individual and collective experiences. The enthusiasm within the FG dynamic may in part have been due to the principle investigator, acting as moderator of the groups. The familiarity with pain management and critical care inspired trust in the participants. However, this may be a disadvantage, as familiarity might also adversely affect the extent to which people feel able to speak freely.

The data analysis in this study requires further exploration into the transcription and translation process for the FG discussions. The FGs were conducted in the Mandarin language and the transcription and translation into English was not validated. The transcription quality is of particular importance for capturing the

emotional and literal meaning in the FG discussions. The accurate translation of the participants' Chinese narration and to some extent how it was stated is important in order to meaningfully present their point of view. To avoid bias, this study employed a bilingual English/Mandarin professional with a PhD in translation during the analysis. This method served as an analytical strategy to keep both the individual and the group present in the text, keeping their stories contextualized and maintaining meaning in a comprehensive way.

7.6.2 Strengths

This study comprised 237 patients separated into two groups. This large population size was served by nurses from the northern, middle and southern health regions in Taiwan. Due to the sample size, diversity in the medical and surgical diagnoses from various ICU settings was realized. This represents a broad sample of patients experiencing acute pain. This acts to make it possible to generalise the findings beyond the current Taiwanese, Chinese speaking population. The use of the qualitative and quantitative approaches in tandem produces a more complete understanding of the difficulties in pain management strategies. The study design was not intended to investigate repeated observations within subjects, as this may contribute to raising the common variance and internal consistency, producing pseudo-higher results (Chen et al. 2011c, Gélinas et al. 2008). Test and retest is a common data collection criteria, however due to the nature of pain and its changes in intensity over time, this method was rejected. The data for this study was generated based on two time points, rest and during both the painful and non-painful procedure. In this manner it is possible to reduce or eliminate the effect of the time differential post stimulus.

Chapter 8 Conclusion

8.1 Introduction

This study represents the first investigative evaluation into the CPOT, BPS and FPRS in the NVCPs in the ICU setting in Taiwan. The study remains unique with its specificity to the Chinese culture and the translation of the BPS and CPOT into the Chinese language. Despite the limitations discussed in Chapter 6, the results provide considerable support for the BPS, CPOT, and FPRS as adequate instruments for rating pain levels in the NVCPs. The thesis aims to increase understanding of the issues of pain severity and that of underestimated pain. It then concludes with recommendations of pain assessment tools for NVCPs. It further explores the process of the translation and adaptation of such instruments, and examines possible strategies for a more clinically appropriate use of these three pain scales.

The thesis focuses on an integrative account of what types of behaviours are manifested when a patient is in pain. This effort required a thorough examination of the established instruments. The alternative frameworks that exist for rating pain have the potential to accommodate multiple aspects of the phenomena related to pain assessment within the ICU setting. It is important to avoid a simplistic overview of pain assessment in NVCPs as this population lack the ability to explain such a complex reality. In Chapter 2, theoretical aspects are addressed to present a detailed picture of the efforts made to understand the psychological and physiological aspects of living with pain. It proposes that further research might

benefit from being formulated and interpreted within the established pain assessment tools.

The main findings of this study will be summarised and the implications for the NVCPs in ICU is addressed. Thereafter the pain management strategies for NVCPs are briefly discussed. To conclude, suggestions with regards for further research and the focus are provided first in the next section of this chapter. The subsequent section draws out implications for pain assessment and critical care strategy for patients who are unable to communicate verbally. Furthermore, recommendations for further research will be provided at the end of this chapter.

8.2 Main findings

NVCPs in the ICU setting require consistent, accurate assessment and appropriate treatment using properly evaluated pain scales for optimum management. The use of a valid behavioural pain scale is recommended in the clinical guidelines for pain assessment in NVCPs (Herr et al. 2006). The BPS and CPOT are recommended by many experts based on critical reviews (Li et al. 2008, Pudas-Tahka et al. 2009, Sessler et al. 2008). This study also shows that the BPS, CPOT and FPRS, when successfully implemented have positive effects on pain assessment and the management of nursing practice in the ICU setting.

The empirical findings are chapter-specific and were summarised within the respective chapters. Quantitative observational survey responses indicate that the expression of pain can be scored validly and reliably using the BPS, CPOT, and FPRS in sedated, mechanically ventilated patients. These ratings are meaningful for at rest and during painful and non-painful procedures. The BPS indicated a greater

sensitivity to change based on statistical criteria for change in the patients' pain levels. The application of an external criterion (comparison with the FPRS) identifying changes in pain levels of the NVCPs, showed a reduction of the BPS to a moderate value for patients with pain stimulus. The qualitative group interviews concluded that the BPS was the pain scale of preference. BPS compared more favourably than the CPOT and FPRS with regard to most of the measures.

The findings of this study are of interest to professionals working with NVCPs. Pain level assessment for NVCPs is rarely reported in the literature. Research in the Chinese population is extremely rare, as such, the current findings offer important insights into patient pain of NVCPs. The findings allow for targeting the weaknesses in the current pain assessment scales. This information is significant and allows for redevelopment and design for more clinically useful pain scales for the NVCPs.

An effective pain assessment plan includes: rating pain intensity (acute vs chronic), treating the cause of pain when possible, familiarity with sedative and analgesic use, and recognizing the minimum threshold for physical and psychological presentation of the patient's pain. Nurses must be well educated in the phenomena of pain and pain management in order to be able to assist patients. The findings of this study may provide important curricular implications for nursing education and research, as well as practical application in the critical care setting.

8.3 Implications and recommendations

8.3.1 Implications for nursing education

At present, nursing education does not adequately address the topic of pain management. This lack is apparent in both the University and College curriculum,

as well as in-house hospital training. Individuals who are unable to communicate their discomfort are at significant risk for inadequate pain management. Some patients may be able to self-report, however there remain difficulties in expressing their experience and potential lack of understanding by health care staff. The inability to distinguish between pain intensity, affect and disability remains a point of possible confusion for both the patient and nurse. As discussed in Chapter 2 in relation to pain measurement, the distinctions identified through research and clinical practice are difficult to measure in the absence of self-report. Patients those are able to respond access a variety of information from different domains when expressing pain behaviours. The simple question ‘How painful is it?’ requires a complex array of physiological as well as psychological feedback from the patient. In most cases this is not readily articulated as the descriptions for pain are often emotive and experienced differently by each patient. Addressing the pain experience in the NVCPs is demanding as the observations by nurse cannot be corroborated by the patient. The information lacking with respect to affective reactions, obscurment due to referred pain, emotional states experienced and efforts at emotional regulation will affect the objective pain rating. As a result, it is virtually impossible to accurately rate the concept of pain. As self-report is not an option, nurses must rely on pain scales that are based on correlations using multiple measures; that reflect similar pain behaviours corresponding to specific pain stimuli. This research evaluated and explored the psychometric properties of the BPS, CPOT, and FPRS in the NVCPs. Increasing our understanding of pain behaviours may guide an improved schema for pain assessment. It is crucial that nurses are aware of patients’ pain and effective

methods to develop pain treatment plans. The inconsistent qualitative finding with respect to feasibility of pain assessment in the NVCPs may be related to lack of familiarity with the specific pain scale. This phenomenon was noted with the CPOT compared to other scales and discussed in Section 6.4.2.8. A component of pain assessment that may not be overlooked is the potential for familiarity and experience with a particular pain scale. This may in turn affect the outcome of the research as well as the accuracy of rating pain in the NVCPs. In this case, the CPOT has a clear advantage due to the verbal component of the scale if patients are able to respond in some manner. Despite the advantage of the verbal component in the CPOT and BPS is the preferred pain scale of use for the NVCPs in the ICU setting. Nurses working with hospitalized patients suffering acute pain must be trained to correctly observe the pain behaviours using selected pain scales. Common pain behaviours that may indicate discomfort in select populations have been identified in this research and in previous studies. Pain behaviours are not necessarily accurate reflections of pain intensity, and in some cases indicate other sources of distress (Pasero & McCaffery 2005). Potential causes and the context of the behaviour must be considered when making treatment decisions. Awareness of individual baseline behaviours and changes that occur with discomfort are very useful in differentiating pain from other causes. Observable indicators should not be considered the most reliable measure of pain and may not replace self-reported pain when a self-report can be obtained (McCaffery & Pasero 1999, Pasero & McCaffery 2005). Critical care nurses and clinicians must remain up to date with the current research regarding new developments in the strategies and tools for assessing pain in ICU populations.

They must remain aware that self-reporting is the most reliable indicator of the presence and intensity of pain (Agency for Health Care Policy and Research 1992). In order to enhance the quality of optimum and multidisciplinary pain management, medical care education should consider offering training in the observational pain behaviour scales throughout health care profession.

8.3.2 Implications for clinical practice in the ICU

Untreated pain has negative physical and psychological consequences (Puntillo, et al., 2009) and may lead to extended hospitalisation. This raises the cost of care due to requiring more resources and nursing time. Institutions would better serve themselves and patients by focusing their money and effort into specific improvements, including; assessment, and the prescription and administration of analgesics. The importance of recognising and assessing acute pain at the earliest opportunity cannot be underestimated.

In the absence of self-report, the observation of pain behaviour is a valid approach to pain assessment. This research highlights the advantages of using the three established pain assessment tools. The study provides valuable information regarding the existing beliefs surrounding pain-associated behaviour patterns, which drive pain pathology. A schema-focused assessment would involve a detailed discussion of the behavioural patterns in NVCPs to identify with which modes the various types of pain behaviour are most clearly linked.

Nurses need to communicate clearly in order to more accurately identify the pain behaviours and their causative agents. The BPS, CPOT, and FPRS are adequate overall. The three scales show validity and reliability in scoring pain intensity of

the NVCPs. The differences between the designs of the three instruments justify their specificity of usage with respect to the type of patient population. These differences relate to the various physiological behaviours of pain expression and how these are observed in current routine clinical procedures. NVCPs may experience different qualities or intensity of pain as compared to other patients and generate specific pain behavioural changes. As such, the multi-dimensional model (BPS or CPOT) is more appropriate than a single observable dimension of pain (FPRS). The multidimensional aspect of the BPS and CPOT has extremely important implications for rating pain in the NVCPs.

8.3.3 Recommendations for future research

The implications of the findings with respect to nursing education and clinical practice were briefly discussed in the previous sections. Pain assessment must be given a higher priority within the clinical context. This remains particularly important as complications in health status of ICU patients have been linked to pain interference. Treatment of the initial diagnosis is often the cause of some of the pain experienced by patients. This factor is unavoidable in the course of ICU hospitalisation, however the effects may be more effectively minimized when known many specific research questions were formulated within the larger framework and several were pursued empirically in the present study (Chapter 5). Based on the Young et al. (2006) study, pain scores were more likely to increase in patients who had not received any analgesics or sedatives in the hour prior to the routine procedure. Additionally, pain levels are more likely to be higher in patients who are ventilated via tracheostomy or who have undergone an operation. Further study is required, and would provide valuable information

on the confounding factors of medications and interventions and their effects on pain. The results of this study may act to guide research on pain assessment. The current findings make it possible to develop more effective approaches to pain assessment, if the mechanisms identified are replicated reliably in future studies.

Sedation is an important confounding parameter in the treatment of mechanically ventilated, critically ill patients. In future studies, it may be possible to develop a pain algorithm in which an analgesic drug is prescribed according to the BPS, CPOT, or FPRS scores induced by endotracheal suction. It would also be possible to use the BPS, CPOT, or FPRS in decision-making when assessing the efficacy of analgesia, and determining the impact of an analgesic titration on patient outcomes. Effective pain management has been shown to reduce the length of time on mechanical ventilation and improve the recovery rate of patients in ICU (Puntillo et al. 2009). Furthermore, the potential use of pain behavioural scales in conjunction with the sedation/agitation scales in use, such as the RASS or MASS; need to be a rewarding area for future research. The use of different painful procedures and the behavioural aversive response to pain requires more research to develop such database of pain behaviour observations. Further investigation of the pain scores due to various routine procedures in the ICU setting may be useful in further validating the three pain scales. Sitting up, walking, and coughing are all important activities following surgery, but may cause increased pain at or around the incision site. A recent study demonstrated that care providers and patients differ in their interpretation of the post-operative scores when using the Numerical Rating Scale (van Dijk Jf Fau - van Wijck et al. 2012). A risk of over-treatment arises when health care providers rigidly follow

guidelines that recommend the prescription of strong analgesics for overestimated pain scores. Further investigation requires analysis of the manner in which the observational pain scales are used and the effect on the pain score. The BPS, CPOT, and FPRS were not compared with the gold standard of pain intensity assessment, the patients' self-report, due to the study focus of interest that the patients were unable to provide a self-report score. Although the criterion validity could not be measured, the scales were tested on patients using the BPS, CPOT and FPRS simultaneously. Further study might explore the use of a self-reported assessment by subjects prior to comparisons with other pain scales. This is of interest as it will allow for greater understanding of how the scales may be used in the decision-making process of pain evaluation and treatment planning. Additionally, efficacy of the use of pain scales may benefit from further study from the perspective of the patients' experience. The benefits of the use of pain scales for both the health care system and care providers in the pain treatment management of NVCPs requires further qualitative research. The question of whether there are benefits for patients or staff members arising from incorporating behavioural pain scales into the care of the nonverbal patients with pain remains a subject for further qualitative research.

8.4 Summary

This study has conclusively demonstrated the validity of the BPS, CPOT, and FPRS. All three scales are able to detect changes in pain levels associated with a painful routine procedure. The results show that traditional pain indicators, such as fluctuations in physiological parameters, do not always provide an accurate measure for assessing pain in critically ill NVCPs. It has been demonstrated that valid

behavioural pain scales developed for critically ill NVCPs support critical care nurses in pain assessment of these patients. The use of these scales can be readily taught and implemented in the ICU. Further research into the use of the behavioural pain scales is required to enhance pain management delivery to critically ill unconscious patients. Based on the current study, consideration to potentially refining the BPS or CPOT would be beneficial. Through combining the strengths of these pain scales, a modified tool that can better evaluate NVCPs will improve pain management in future clinical ICU practice.

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Appendix

1: Behavioural Pain Scale

Item	Description	Score
Facial expression	Relaxed	1
	Partially tightened (e.g. brow lowering)	2
	Fully tightened (e.g. eyelid closing)	3
	Grimacing	4
Upper limbs	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Compliance with ventilation	Tolerating movement	1
	Coughing with movement	2
	Fighting ventilator	3
	Unable to control ventilation	4

(Payen *et al.* 2001)

2: Critical-Care Pain Observation Tool

Indicator	Description	Score	
Facial expression	No muscular tension observed	Relaxed, neutral	0
	Presence of frowning, brow lowering, orbit tightening, and levator contraction	Tense	1
	All of the above facial movements plus eyelid tightly closed	Grimacing	2
Body movements	Does not move at all (does not necessarily mean absence of pain)	Absence of movements	0
	Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements	Protection	1
	Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed	Restlessness	2
Muscle tension	No resistance to passive movements	Relaxed	0
Evaluation by passive flexion and extension of upper extremities	Resistance to passive movements	Tense, rigid	1
	Strong resistance to passive movements, inability to complete them	Very tense or rigid	2
Compliance with the ventilator (intubated patients)	Alarms not activated, easy ventilation	Tolerating ventilator or movement	0
	Alarms stop spontaneously	Coughing but tolerating	1
	Asynchrony: blocking ventilation, alarms frequently activated	Fighting ventilator	2
OR	Talking in normal tone or no sound	Talking in normal tone or no sound	0
Vocalization (extubated patients)	Sighing, moaning	Sighing, moaning	
	Crying out, sobbing	Crying out, sobbing	1
			2
Total, range			

(Gélinas *et al.* 2006).

3: Face Pain Rating Scale



1983 Wong-Baker FACE Foundation. Used with permission

(Wong & Baker 1983)

4: Certificate of University Institutional Review Board

The University of Edinburgh
College of Humanities and Social Science

SCHOOL OF HEALTH IN SOCIAL SCIENCE

APPROVAL BY SUBJECT AREA RESEARCH ETHICS TEAM/ CO-ORDINATOR (LEVEL 2)

Research Ethics Committee Number:	N/A
Name/s of Researcher/s:	Nai-Huan Hsiung
Proposed Title of Research:	An examination of behavioural parameters pain scales in critically ill, sedated and mechanically ventilated patients
Funding Body (if appropriate):	Self funding
General Comments:	
Outcome: (please tick box)	Approved <input checked="" type="checkbox"/> Approved with Conditions (see attached) <input type="checkbox"/> Not Approved <input type="checkbox"/>
If approved with conditions, name of person to oversee these:	
<p>The above research proposal has been approved by the subject area research ethics team/co-ordinator.</p> <p>Signed: <i>K. N. Melia</i> (Professor Kath Melia) Date: 31-3-11</p> <p>Signed: (name of person) Date:</p>	

5: Certificate of Taipei IRB approval

臺北醫學大學暨附屬醫院聯合人體研究倫理委員會 TMU-Joint Institutional Review Board

通過證明函－簡易審查案

開立日期：民國 100 年 8 月 8 日

本會編號：201104007

計畫名稱：分析並比較疼痛行為量表中文版之信度與效度

計畫主持人：林乾閔

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個案報告表版本/日期：version 1.1 2011/05/15

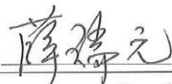
上述計畫已通過本會簡易審查程序，將於民國 100 年 9 月 1 日經本會第 42 次會期追認，特此證明。試驗有效期至民國 101 年 8 月 7 日，為期一年。試驗期間應接受本委員會之監督。

依據衛生署與 ICH-GCP 規定，後續追蹤程序及要求如下：

1. 期中報告：依期中報告審查頻率每 12 個月繳交期中報告。有效期限屆滿時若尚未通過期中報告與效期展延審查者，試驗不得繼續執行。
2. 追蹤報告：應依本委員會審查通過時之決議，定期繳交至本委員會審查。
3. 結案報告：試驗完成後，應將執行情形及結果依結案報告表要求送至本委員會審查。試驗結束後三個月仍未繳交者，不得申請新試驗案之審查。
4. 嚴重不良事件(SAE)報告：試驗主持人應根據衛生署「藥品優良臨床試驗準則」和「嚴重藥物不良反應通報辦法」規定，辦理相關事宜。

主任委員

薛瑞元



Certificate of IRB Approval TMU-Joint Institutional Review Board

Approval No. : 201104007

Protocol Title : An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients

Principle Investigators : Chien-Min Lin

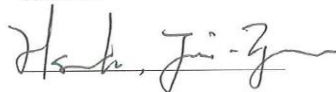
Protocol No. /Version/Date : version 1.3 2011/07/31

Informed Consent Forms : version 1.3 2011/07/31

Case Report Forms : version 1.1 2011/05/15

The above study has been approved by expedited review process of the TMU-Joint Institutional Review Board on September 1, 2011, valid August 7, 2012, and accepts the monitoring of TMU-JIRB.

Jui-Yuan Hsueh, M.D.,
Chairman



TMU-JIRB 98-09-A

FDC00076

6: Certificate of Hualien IRB approval



Buddhist Tzu Chi General Hospital Research Ethics Committee

707, Sec. 3, Chung-Yang Rd., Hualien, 97002, Taiwan
Tel: 886-3-8561825 Ext. 2124 Fax: 886-3-8561825 Ext. 3272

Certificate of Approval

The following documents have been submitted for review.

Protocol Number: IRB100-23

Protocol Title: An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients

Principal Investigator: Nai-Huan Hsiung
Department of Nursing, Tzu Chi College of Technology

Protocol Version: 1.0, March/15/2011

Informed Consent Form Version: 1.0, March/15/2011

Approval Dated: April/28/2011

Approval Expires: March/31/2012

According to ICH-GCP, Institutional Review Board will have to review each clinical research case annually and decide whether continue it or not. Therefore, please send us your Interim Reports concerning the progress of the project, when requested. By the end of this project you may be asked to inform the Committee on the status of your project. If this has been completed, please send us your Final Report. If this has not been completed, you may request renewed approval at that time.

You are reminded that a change in protocol in this project requires its resubmission to the Committee and approval by the Committee before incorporating the changes. Also, the principal investigator must report to the Chair of the Research Ethics Committee promptly, and in writing, any unanticipated problems involving risks to the subjects or others, such as adverse reactions to biological drugs, radio-isotopes or to medical devices.



Hann-Chorng Kuo, M.D.
Chairman, Research Ethics Committee

E6A0021538-05

7: Certificate of Taichung IRB approval

正本

檔號：
保存年限：

財團法人佛教慈濟綜合醫院台中分院 函

機關地址：42743 台中市潭子區豐興路一段66號
承辦人：景艷霞
傳真：(04) 3602-0123
電話：(04) 3606-0666 分機：1479

97005
花蓮市建國路二段880號

受文者：慈濟技術學院護理系

發文日期：中華民國一〇一年三月廿九日
發文文號：慈中醫文字第1000237號
速別：速件
密等及解密條件：普通
附件：

主旨：感恩 慈濟技術學院來函，函文希望於本院第一、第二
加護病房收案進行「分析並比較疼痛行為量表中文版之
信度與校度」研究，說明如下，請 諒察。

說明：

依本院協助學術研究作業辦法，凡申請協助學術研究，請檢附
下列資料：

- 一、學術研究計畫摘要。
- 二、學術調查工具(如問卷、評估表、量表)。
- 三、IRB核准函(本院目前尚未辦理審查作業，請送花蓮研究
倫理為員會審查)。
- 四、填寫協助學術研究申請表、同意書。敬覆，請 諒達



正本：慈濟技術學院護理系
副本：本院護理部、本院研究部

代理院長 陳子勇

1000002173



人體試驗審查委員會臨床試驗案同意函

臨床試驗案名稱：分析並比較疼痛行為量表中文版本之信度與效度

本院申請人（主持人）：本院協同：廖泓峰（主持人：熊乃歡）

案件編號（包括版本）：00-IRB-006-M（第一版）

計畫書版本：第一版，Sep., 21, 2011

受試者同意書版本：第一版，Sep., 21, 2011

個案報告版本：Nil.

上述臨床試驗案於(西元) 2011 年 9 月 21 日經本院人體試驗審查委員會審查通過，特此證明。本會組織與執行皆遵守 ICH-GCP 規範。

本臨床試驗案執行期間自 2011 年 9 月 21 日至 2012 年 7 月 31 日。

Buddhist Tzu Chi General Hospital Taipei Branch Institutional Review Board Approval Letter

Protocol Title: An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients

Principal Investigator:

Ming-Feng Liao (Investigator in the Buddhist Tzu Chi General Hospital Taipei Branch),

Nai-Huan Hsiung (The Principal Investigator of this study)

Protocol No.: 00-IRB-006-M (version 1)

Protocol: version 1, Sep., 21, 2011

Inform consent form: version 1, Sep., 21, 2011

Case report form: Nil.

The above study has been approved by the Buddhist Tzu Chi General Hospital - Taipei Branch Institutional Review Board on Sep., 21, 2011. The constitution and operation of this review board are according to the guidelines of ICH-GCP.

The above study conduction time is from Sep., 21, 2011 to Jul., 31, 2011

人體試驗審查委員會 主任委員

Chairman, Institutional Review Board

(簽名)

廖 剴 毅

Chiau-Suong Liao

(Chiau-Suong Liao)

日期：(西元) 2011 年 09 月 21 日

Date (M/D/Y): 09 / 21 / 2011

E6A0021879-F3

8: Certificate of Chia-Yi IRB approval

BUDDHIST DALIN TZU CHI GENERAL HOSPITAL

BUDDHIST DALIN TZU CHI GENERAL HOSPITAL
2, Min-Sheng Road, Dalin Town, Chia-Yi
TAIWAN R.O.C. (622)
TEL:05-2648000
FAX:05-2648999



財團法人佛教慈濟綜合醫院
大林分院 (622)
嘉義縣大林鎮民生路2號
電話：(05)2648000
傳真：(05)2648999

Research Ethics Committee of the Dalin Tzuchi General Hospital

Certificate of Approval

The following documents have been submitted for review.

Protocol Title : An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients

Protocol No./IRB No. : B10002014

Chief Principal Investigator : Nai-Huan Hsiung

Informed Consent Form : May/24/2011

Board Meeting/Approval Date : Jun/29/2011

Study Approval Expires : Dec/31/2011

Yours sincerely,

Lee-Yi Kung

Chairman

Institutional Review Board

Taiwan R.O.C.

Yi-Kung Lee

E6A0021593-01

\030E051

20本(亞培)

9: Cover letter and informed consent for patients

Dear Respondent,

This letter is an invitation to participate in a research study. As a postgraduate research student in the school of Health in Social Science at the University of Edinburgh, I am currently conducting research under the supervision of Dr. Graeme D. Smith on pain assessment issues in Taiwan. I am also a lecturer of Tzuchi College of Technology.

Purpose of the study:

This survey assesses how validity and reliability of new pain assessment tools in Traditional Chinese version, which is proved by previous foreign studies, including the Behavioural Pain Scale and the Critical-Care Pain Observation Tool.

Description of how confidentiality will be assured and the limits to these assurances:

I do not know of any risks to you if you decide to participate in this survey and I guarantee that your responses will not be identified with you personally. I promise not to share any information that identifies you with anyone outside my research group. Nurse are also requested that cannot put your name on the pain assessment tools in order to administer an anonymous questionnaire.

Description of the survey procedures and approximate duration of the study:

The survey will progress the data collecting during your stay in the intensive care unit. You do not need to take the time to complete any process because the investigation will be carried out by your staff nurses. There is no extra treatment and assessing procedure will apply on my medical statement when I am sedated. Your participation is voluntary. Regardless of whether you choose to participate, please let me know if you would like a summary of my findings.

Anticipated benefits resulting from this study:

You may not benefit directly from taking part in this study. However, this study may help us better understand how to assess pain in patients with verbal inability in the future. Through your participation, I hope that the results of the survey will be useful for pain management in the intensive care unit and I hope to share my results by publishing them in a scientific journal where public all over the world can use them. Respondents will have the opportunity to receive feedback regarding the study results.

Contact information.

If you have any questions about this study, you can contact the person(s) below:

Postgraduate Student	Supervisor
Nai-Huan Hsiung BA, MSc, RN Postgraduate research student Nursing Studies The University of Edinburgh Medical School Teviot Place Edinburgh EH8 9AG Tel: 0131 545 2903 ; +886928569093 e-mail addresses : N.Hsiung@sms.ed.ac.uk	Graeme D. Smith BA, PhD, RGN Nursing Studies The University of Edinburgh Medical School Teviot Place Edinburgh EH8 9AG Tel: 0131 650 3901 e-mail addresses : Graeme.Smith@ed.ac.uk

I confirm that this research project has been reviewed by the Human Research Ethic Review Boards and I have carried out the School Ethics self-audit in relation to Nai-Huan Hsiung and Dr. Graeme D. Smith project **An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients** and that no reasonably foreseeable ethical risks have been identified. If you have any concerns about your rights as a participant in this study you may contact the School of Health in Social Science Ethics Committee or the hospital Ethics Committee: Contact telephone Number:

I hope that you will be able to participate in this study.

Sincerely,

Nai-HuanHsiung

An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients

CONSENT

I have read the information presented in the information letter about a study being conducted by a postgraduate research student in the school of Health in Social Science at the University of Edinburgh. If I consent to participate in this study I will complete a series of clinical trials. These include routinely painful / non-painful care procedures and using pain assessment tools to assess my pain experiences during I am sedated and ventilated in the intensive care unit. I understand that I (my family) may refuse to participate in this study and am free to cease participating at any time after the study has started.

I understand that I (my family) will be asked to consent to allowing the researchers access to my academic records. The knowledge gained from this study may contribute to facilitate pain measurement in unconscious or sedated patient. All individual research results will be kept confidential. Results will only be reported in group form and I will be provided with a group summary of the results on request.

I am also aware that this project has been reviewed by Level 1 Ethics, and received ethics clearance through, the Committee of Research Ethics at the University of Edinburgh and the Human Research Ethic Review Board. There are no predictable physical ill effects associated with participating in this study. I understand that I am completely free to refuse to answer any question without penalty.

With full knowledge of all foregoing, I agree (my family), of my own free will, to participate in this study.

Participant _____ Name: _____
(Please print)

Participant Signature: _____

(Participant's legal guardian)

Date: _____

10: Cover letter and Informed Consent for Nurses

CONSENT FORM: FOCUS GROUPS

We are asking you to participate in a study about pain assessment for nonverbal patients in critical care. This consent form should give you the information you need to decide whether to be in the study. We welcome your questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.” We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of the study is to learn how health workers view their jobs on pain assessment for nonverbal patients, how satisfied they are with the use and the feasibility of new pain assessment tools. We hope to learn what things the Ministry of Health and other health care could do to improve the pain assessment and other factors that would improve pain management in the intensive care.

STUDY PROCEDURES

There will be a focus group for nurses. The focus groups will take 45 to 60 minutes, depending on the number of people. We would like to tape the focus groups so they can be transcribed. No names will be attached to the focus groups, and the tapes will be destroyed as soon as they are transcribed, or within three months, whichever comes first. We request that any supervisory employees be excused from these groups.

RISKS, STRESS, OR DISCOMFORT

We do not anticipate that the questions will be difficult to answer, but some may cause you to think about working conditions that are distressing and may cause emotional discomfort. You may refuse to answer any question at any time, leave the focus group at any time, and may withdraw from the study at any time without penalty.

CONFIDENTIALITY

No findings in this study will be linked to individual respondents. We will ask participants to respect each other's confidentiality, but we cannot ensure this.

Ministry of Health employees or your employers will not have access to interview notes or individual questionnaires. Data will be handled by data entry clerks, student researchers from the University of Edinburgh.

Contact information.

If you have any questions about this study, you can contact the person(s) below:

Postgraduate Student	Supervisor
Nai-HuanHsiung BA, MSc, RN Postgraduate research student Nursing Studies The University of Edinburgh Medical School Teviot Place Edinburgh EH8 9AG Tel: 0131 545 2903 ; +886928569093 e-mail addresses : N.Hsiung@sms.ed.ac.uk	Graeme D. Smith BA, PhD, RGN Nursing Studies The University of Edinburgh Medical School Teviot Place Edinburgh EH8 9AG Tel: 0131 650 3901 e-mail addresses : Graeme.Smith@ed.ac.uk

Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above.

I agree to

- ☐ Participate in a focus group.
- ☐ Have the focus group taped.

Printed name of participant

Signature

Date

11: Acute Physiology and Chronic Health Evaluation

Physiologic Variable	High Abnormal Range					Low Abnormal Range					Points
	+4	+3	+2	+1	0	+1	+2	+3	+4		
Temperature - rectal (°C)	≥ 41	39-40.9		38.5-38.9	36-38.4	34-35.9	32-33.9	30-31.9	≤ 29.9		
Mean Arterial Pressure - mm Hg	≥160	130-159	110-129		70-109		50-69		≤ 49		
Heart Rate (ventricular response)	≥180	140-179	110-139		70-109		55-69	40-54	≤ 39		
Respiratory Rate (non-ventilated or ventilated)	≥ 50	35-49		25-34	12-24	10-11	6-9		≤ 5		
Oxygenation: A-aDO ₂ or PaO ₂ (mm Hg) a. FIO ₂ ≥0.5 record A-aDO ₂ b. FIO ₂ <0.5 record PaO ₂	≥500	350-499	200-349		< 200 PO ₂ >70	PO ₂ 61- 70		PO ₂ 55-60	PO ₂ <55		
Arterial pH (preferred) Serum HCO ₃ (venous mEq/l) (not preferred, but may use if no ABGs)	≥7.7 ≥52	7.6-7.69 41-51.9		7.5-7.59 32-40.9	7.33-7.49 22-31.9		7.25-7.32 18-21.9	7.15-7.24 15-17.9	<7.15 <15		
Serum Sodium (mEq/l)	≥180	160-179	155-159	150-154	130-149		120-129	111-119	≤110		
Serum Potassium (mEq/l)	≥7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		<2.5		
Serum Creatinine (mg/dl) Double point score for acute renal failure	≥3.5	2-3.4	1.5-1.9		0.6-1.4		<0.6				
Hematocrit (%)	≥60		50-59.9	46-49.9	30-45.9		20-29.9		<20		
White Blood Count (total/mm ³) (in 1000s)	≥40		20-39.9	15-19.9	3-14.9		1-2.9		<1		
Glasgow Coma Score (GCS) Score = 15 minus actual GCS											
A. Total Acute Physiology Score (sum of 12 above points)											
B. Age points (years) ≤44 = 0; 45 to 54 = 2; 55 to 64 = 3; 65 to 74 = 5; ≥75 = 6											
C. Chronic Health Points (see below)											
Total APACHE II Score (add together the points from A+B+C)											

12: Glasgow Coma Scale

The Glasgow Coma Scale					
Eye opening		Verbal Response		Motor Response	
				Obeys command	6
		Orientated	5	Localising pain	5
Spontaneous	4	Confused speech	4	Flexion withdrawal	4
To command	3	Inappropriate words	3	Abnormal flexion (decorticate)	3
To pain	2	Incomprehensible sounds	2	Extension response (decerebrate)	2
None	1	None	1	None	1

13: Richmond Agitation–Sedation Scale

Richmond Agitation Sedation Scale (RASS) *

Score	Term	Description	
+4	Combative	Overtly combative, violent, immediate danger to staff	
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive	
+2	Agitated	Frequent non-purposeful movement, fights ventilator	
+1	Restless	Anxious but movements not aggressive vigorous	
0	Alert and calm		
-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to <i>voice</i> (≥ 10 seconds)	Verbal Stimulation
-2	Light sedation	Briefly awakens with eye contact to <i>voice</i> (< 10 seconds)	
-3	Moderate sedation	Movement or eye opening to <i>voice</i> (but no eye contact)	
-4	Deep sedation	No response to voice, but movement or eye opening to <i>physical</i> stimulation	Physical Stimulation
-5	Unarousable	No response to <i>voice or physical</i> stimulation	

Procedure for RASS Assessment

1. Observe patient
 - a. Patient is alert, restless, or agitated. (score 0 to +4)
2. If not alert, state patient's name and *say* to open eyes and look at speaker.
 - b. Patient awakens with sustained eye opening and eye contact. (score -1)
 - c. Patient awakens with eye opening and eye contact, but not sustained. (score -2)
 - d. Patient has any movement in response to voice but no eye contact. (score -3)
3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.
 - e. Patient has any movement to physical stimulation. (score -4)
 - f. Patient has no response to any stimulation. (score -5)

* Sessler CN, Gosnell M, Grap MJ, Brophy GT, O'Neal PV, Keane KA et al. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care patients. *Am J Respir Crit Care Med* 2002; 166:1338-1344.

* Ely EW, Truman B, Shintani A, Thomason JWW, Wheeler AP, Gordon S et al. Monitoring sedation status over time in ICU patients: the reliability and validity of the Richmond Agitation Sedation Scale (RASS). *JAMA* 2003; 289:2983-2991.

14: Permission to translate BPS and CPOT

2014年1月26日

Mail :: Study Re: Permission to translate the pain scale

Date: Fri, 08 Apr 2011 14:02:51 +0200 [08/04/2011 13:02:51 GMT]

From: Jean-Francois Payen <Jean-Francois.Payen@ujf-grenoble.fr>

To: Nai-Huan Hsiung <N.Hsiung@sms.ed.ac.uk>

Subject: Re: Permission to translate the pain scale

X-Spam-Score: 0

Dear Nai-Huan,

Thank you for your message. Of course, you have my permission to use the BPS and translate it into the traditional Chinese version.

Pr JF Payen

Le 08/04/11 04:50, Nai-Huan Hsiung a écrit :

Dear Dr. Payen,

This is a request from a PhD student of the University of Edinburgh, UK. First, I want to introduce myself. I was a Taiwanese lecturer of Nursing and Pain Management in Buddhist Tzu Chi College of Technology. Since I am very interested in pain management, it is definitely the main subject in my PhD study. My proposed title of research is "An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients" with supervisions of Dr. Graeme D. Smith and Dr. Jennifer Tocher. This study project attempts to demonstrate that the expression of pain can be scored validly and reliably by using the Traditional Chinese version of the BPS and the Critical-Care Pain Observation Tool (CPOT) in sedated, mechanically ventilated patients and the comparison of their effectiveness. Although BPS has been translated into the Traditional Chinese's version by Yen-Ya Chen and I got her permission to use, I still hope I could obtain your permission to translate BPS into the traditional Chinese version, in order to compare their difference of validity and reliability.

Thank you very much and sorry if I am rude in advance because this is my first time to make this kind of request. Please let me know if something was missed by me.

Kind regards,

Lainey (Nai-Huan) Hsiung
PhD Student
School of Health in Social Science
University of Edinburgh
Medical School
Teviot Place
Edinburgh EH8 9AG
Scotland UK

2014年1月26日

Mail :: Study: RE: Permission to translate the pain scale

Date: Tue, 22 Feb 2011 14:29:41 -0500 [22/02/2011 19:29:41 GMT]

From: Céline Gélinas, Dr. <celine.gelinas@mcgill.ca>

To: Nai-Huan Hsiung <N.Hsiung@sms.ed.ac.uk>

Cc: hsiung@tccn.edu.tw <hsiung@tccn.edu.tw>,
Graeme.Smith@ed.ac.uk <Graeme.Smith@ed.ac.uk>,
Jennifer.Tocher@ed.ac.uk <Jennifer.Tocher@ed.ac.uk>

Subject: RE: Permission to translate the pain scale

X-Spam-Score: 0

Priority: 1

Dear Nai-Huan,

Thank you for your interest in the CPOT. I know people who have translated the CPOT into Chinese language. A first step would be to be in touch with them.

From Taiwan:
Chen, Huei-Jiun
hjchen@vghtc.gov.tw

Li Hua Cheng
hwa0918111719@yahoo.com.tw

From Dalian:
Dr Li Qingdong
liqingdong2@163.com

Please keep me posted. Don't hesitate to let me know if you have any other questions.

Celine

From: Nai-Huan Hsiung [N.Hsiung@sms.ed.ac.uk]
Sent: February 13, 2011 10:07 AM
To: Céline Gélinas, Dr.
Cc: hsiung@tccn.edu.tw; Graeme.Smith@ed.ac.uk; Jennifer.Tocher@ed.ac.uk
Subject: Permission to translate the pain scale

Dear Dr. Céline Gélinas,

This is a request from a PhD student in the University of Edinburgh, UK. First, I want to introduce myself. I am a Taiwanese lecturer of Nursing and Pain Management in Buddhist Tzu Chi College of Technology and went to UK for further education in 2009. Since I am very interested in pain management, it is definitely the main subject in my PhD study. My proposed title of research is "An examination of Behavioural Parameters Pain Scales in Critically Ill, Sedated and Mechanically Ventilated Patients" with supervisions of Dr. Graeme D. Smith and Dr. Jennifer Tocher. This study project attempts to demonstrate that the expression of pain can be scored validly and reliably by using the Traditional Chinese version of the BPS and the CPOT in sedated, mechanically ventilated patients and the comparison of their effectiveness. Therefore, I hope I could obtain your permission to translate the Critical-Care Pain Observation Tool into the traditional Chinese version, so that Taiwanese and Chinese could have more effective pain management if it could be developed and validated.

https://www.staffmail.ed.ac.uk/imp/message.php?actionID=print_message&mailbox=Study&index=1&uniq=1390699781125

1/2

2014年1月26日

Mail :: Study RE: Permission to translate the pain scale

Thank you very much and sorry if I am rude in advance because this is my first time to make this kind of request. Please let me know if something was missed by me.

Kind regards,

Nai-Huan Hsiung
Research Student
School of Health in Social Science
University of Edinburgh
Medical School
Teviot Place
Edinburgh EH8 9AG
Scotland UK

--

The University of Edinburgh is a charitable body, registered in Scotland, with registration number SC005336.

15: Photocopies of relevant published papers

British Journal of Pain

<http://bjp.sagepub.com/>

Acute Pain

British Journal of Pain 2013 7: 5
DOI: 10.1177/2049463713481587

The online version of this article can be found at:
http://bjp.sagepub.com/content/7/2_suppl/5

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On behalf of:



THE BRITISH PAIN SOCIETY
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023

NURSES' VIEWS ABOUT ASSESSING PAIN IN NONVERBAL PATIENTS BY USING BEHAVIOURS PARAMETRIC PAIN SCALES IN THE INTENSIVE CARE

Category: ASSESSMENT & MEASUREMENT
Nai-Huan Hsiung^{1,2}, Graeme Smith¹, Jennifer Tocher¹

¹The University of Edinburgh, Edinburgh, UK; ²Tzu-chi College of Technology, Hualien, Taiwan

Background

The inadequate treatment of pain in adults with speech impairments could be due to professional caregivers' failure to assess and manage pain effectively. It is recognized that effective pain assessment would lead to more satisfied patients and families. Despite the availability of the evidence to guide pain management practices, practices are often suboptimal with patients experiencing from moderate to severe pain in critical care. Limited theoretical knowledge and lack of objective instruments for assessing pain have been suggested reasons for this. This study, then, is to explore nurses' views on the use of pain assessment tools in an intensive care (ICU) setting.

Methods

This paper present data from three modified focus groups undertaken as part of a large study by exploring pain assessment practices in five hospitals in Taiwan. The researcher first introduced various pain assessment scales for measuring pain in patients with communicative difficulties, such as the BPS (Behavioural Pain Scale), the CPOT (Critical-care Pain Observation Tool), and the FRPS (Facial Rating Pain Scale). Before the study, twenty two nurses were taught how to appropriately assess patients by using the three scales. After practicing with them for more than half a year, fifteen nurses took part in the focus groups and were asked questions about their views on the satisfaction and remarks of using three instruments in pain assessment within the ICU.

Results

The regional Research Ethic Committee in Hualien, Taipei, and Chiayi approved the study (approval no. IRB100-23, B10002014, 00-IRB-006-M). All participated nurses agreed that the introduction of pain assessment tools would improve documentation. Nurses also felt full theoretical knowledge on overt expressions of pain behaviours is necessary to objectively explore pain in patients with speech impairment. Therefore, almost three-quarters of nurses preferred BPS for assessing pain in their clinical practices. When nurses were asked how much time they need and how easy they felt for completing these tools, all of them agreed that each patient assessment was the easiest and took minimal time to use FRPS. However, eighty percent considered that the most effective pain reactions during nociceptive procedures had been assessed by using BPS. Even though all stated CPOT provides a detailed item-description about pain behaviours, there is also main obstacle to use because of its ambiguous indicators.

Conclusion

The variety of pain assessments used by nurses in this study opens an avenue for further investigating through the linkage between underlying conceptions of pain behaviours and the effectiveness of nurses' assessments of pain in patients without verbal communication by using an objective pain measurement. The inconsistencies in these replies could reflect the conflicting demands between the need to use a validated measures of pain for nonverbal patients while managing a heavy workload in ICU.

024

PAIN CLINIC - PATIENT SATISFACTION SURVEY

Category: ASSESSMENT & MEASUREMENT
Arindam De, Nick Roberts

Kettering General Hospital, Kettering, UK

Background

Pain Clinic - Patient Satisfaction Survey was developed as a unique patient centered reflective feedback loop at Kettering General Hospital Pain Clinic. More than 3000 chronic pain patients were seen in clinic last year and offered consultation for over 1000 new referrals in last one year. We offer the best available management for Chronic Pain based on recent advances and available evidences. But effectiveness of our service was only endorsed recently by patients following this survey.

Methods

Prospective survey recruited 100 new patients over 3 months, who were requested to fill the questionnaire. The questions covered the following: The reason for consultation and their expectations from the clinic, choices include -

- Someone to listen
- Diagnose the problem
- Further Investigations
- Medication
- Injection
- Acupuncture
- Alternative therapies (TENS)
- Cure
- Coping skills
- Improve quality of life

They were also asked where would they like the consultation - either at the hospital or at the GP / PCT and how far they were prepared to travel for this.

The duration of the consultation and the information given were satisfactory or not.

Patient understanding of the management plan and professionalism of both the doctors and the nurses were in the questionnaire.

Finally they were requested to value their appointment by putting a number between 0 to 10; 0 being waste of time to 10 being most satisfactory. Patients were also requested to add comments regarding consultation.

Results

Out of 100, 6 refrained from valuing, 3 did not reply.

> 70% patients expected someone to listen, diagnose a problem, investigate and offer medications and injections.

Majority did not expect cure but wanted a better quality of life.

80% expect consultation at local hospital.

90% were happy with timing of referral and the length of consultation where they understood the given information, except for the leaflets. Patients rated doctors and nurses as professionals.

Value of the appointment mostly had high scores, which then plotted in Net Promoter Score (NPS) chart.

NPS is a customer loyalty model of Harvard Business School to improve services, which correlates with revenue growth. NPS seeks votes on a scale 0-10 for a service; where 0-6 detractors, 7-8 passives and 9-10 are promoters. NPS is calculated as (% promoters) - (% detractors). NPS maximum score can be 100 (everyone promoter), NPS +50 is excellent. Our survey yields NPS of 82.



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2-43

Paediatric restless legs syndrome is associated with multiple pain syndromes

David Champion¹ Rianne Kofman² Cindy Chapman¹ Tiina Jaaniste¹ Carl von Baeyer³ John Hopper¹

¹⁾ Australia ²⁾ Netherlands ³⁾ Canada

2-44

Parent and child predictors of protective parental responses to chronic pediatric pain

Jessica W. Guite¹ Robyn Lewis Claar¹ Karen J. Kaczynski¹ Deirdre E. Logan¹

¹⁾ United States

2-45

Twin study of one month current prevalence of regional pain in adolescents

Rianne Kofman¹ Cindy Chapman² David Champion² Tiina Jaaniste² Janny Germs¹ John Hopper²

¹⁾ Netherlands ²⁾ Australia

2-46

Growing pains: genetic influence and associations including restless legs syndrome

Matthew Crawford¹ David Champion¹ Cindy Chapman¹ Tiina Jaaniste¹ John Hopper¹ Sam Berkovic¹

¹⁾ Australia

2-47

Paediatric migraine: twin family car-control study of heritability and associations

David Champion¹ Cindy Chapman¹ Lannie Ligthart² Shamini Gunalan¹ Tiina Jaaniste¹ John Hopper¹

¹⁾ Australia ²⁾ Netherlands

2-48

Siblings' experiences of pain in children with Cerebral Palsy

Petra Lostelius¹ Annacristine Fjellman-Wiklund¹

¹⁾ Sweden

2-49

Parental Attitudes Towards Children's Pain and Analgesic Drugs in the UK

Alison Twycross¹ Anna Williams¹ Rachael Bolland¹ Robin Sunderland¹

¹⁾ United Kingdom

2-50

Effects of a support program for parents of children with chronic debilitating pain

Camilla Wiwe¹ Marie Kanstrup¹ Mike Kemani¹ Linda Holmström¹ Rikard Wicksell¹

¹⁾ Sweden

2-51

Acute Pain: Perception of Children and Adolescents' Mothers, Value and Impact

Sílvia Barbosa¹ Patricia Rangel¹ Manuela Fragomeni¹

¹⁾ Brazil

2-52

Development of the Parent Responses to School Functioning (PRSF) Measure

Barber Garcia Brittany¹ Deirdre Logan¹

¹⁾ United States

2-53

Chronic pain in the school setting: the teachers' point of view

Ester Solé¹ Jordi Miró¹ ¹⁾ Spain

2-54

Satisfaction with parent participation in children's immunization pain reduction

F. Ralph Berberich¹ Linda Franck¹ Anna Taddio²

¹⁾ United States ²⁾ Canada

2-55

A pilot randomized trial of parent participation in child immunization pain reduction

Linda Franck¹ F. Ralph Berberich¹ Anna Taddio²

¹⁾ United States ²⁾ Canada

2-56

Restoring School Functioning in Children with Chronic Pain: Multifaceted Intervention in a Pediatric Pain Rehabilitation Program

Julie Collier¹ Jody Thomas¹ Thayer Gershon¹ Elliot Krane¹

¹⁾ United States

2-57

Pain syndrome correlates with raised level of cortisol, cytokine, C-reactive protein.

Dmytro Dmytriev¹ Levgenii Vzhetsion¹ Oleksandr Mazulov¹ Oleksandr Nazarchuk¹ Oksana Goncharuk¹ Nataliia Kosechenko¹

¹⁾ Ukraine

16: Examples of consent's documents in traditional Chinese version

試驗計畫書編號

TMU-JIRB

林乾閔

臺北醫學大學暨附屬醫院聯合人體研究倫理委員會
TMU-Joint Institutional Review Board
臨床受試者同意書

計劃名稱：	
分析並比較疼痛行為量表中文版本之信度與效度	
執行單位：雙和醫院	神經外科部
萬芳醫院	神經外科部
北醫附設醫院	神經外科部
英國愛丁堡大學護理研究所	
電話：(02)2249-0088#8120	
電話：(02)29307930#6942	
電話：(02)27372181#3918	
電話：+44131 650 3889	
計畫主持人：林乾閔	職稱：主治醫師
協同主持人：陳淑美、吳忠哲	職稱：主治醫師
※醫院 24 小時緊急聯絡人※：熊乃歡 電話：0928569093	
受試者姓名：	性別：
出生日期：	年齡：
病歷號碼：	
通訊地址：	
電話：	
緊急聯絡人姓名/與受試者關係：	
通訊地址：	
電話：	

1. 試驗背景：

您(的家人)已受邀以自願的方式參加這項研究計畫，計畫中所使用的研究工具是由法國學者 Dr. Payen 及加拿大學者 Dr. Gélinas 發展出來的新型疼痛行為評估量表，他們的原理為人類對於疼痛的刺激會產生全身的行為改變，以了解患者的疼痛程度。除法國外，摩洛哥、澳洲及加拿大等國家已經臨床上使用這些工具檢查評估意識不清且使用呼吸器患者的疼痛，顯示這些量表有很好的可信度及效度，安全性相當高。您可以放心，這種檢查也不會產生任何副作用。

您(的家人)參加的這項研究計畫將會持續 12 個月，全台灣預計約有 360 位患者將參與這項研究。請您在同意參加這項研究計畫之前，先充分了解此份同意書的內容。這份同意書內容包括試驗目的、試驗方法與程序、可能的益處、可能的危險、不舒服及注意事項。同意書也提及其他的治療方法和您(的家人)可以隨時終止參加本研究的權利。如果您(的家人)同意參加本研究，您將會收到這份同意書的副本。

2. 試驗目的

本研究計畫的目的是為了要確定以下研究的問題：

將國外所研發的疼痛行為評估量表翻譯成中文版本後，(1)它們是否可以同樣成為評估意識不清且使用呼吸器的患者一個可信又有效的疼痛評估工具；(2)它們是否適用在講中文的語言環境，使加護病房重症患者在無法表達其疼痛時，醫護人員可使用它們，了解患者的疼痛程度，進而讓患者獲得良好的疼痛處理。

3.試驗程序及受試者納入、排除條件

執行本研究計畫的醫師或相關研究人員將會與您討論有關參加本研究的必要條件。請您配合必須誠實告知我們您(的家人)過去的健康情形，若您(的家人)有不適合參加本研究的情況，將不能參加本研究計畫。

參加本研究計畫的條件：

- 您(的家人)必須年滿 20 歲。
- 您(的家人)血液動力學穩定並無接受過心肺復甦術。
- 您(的家人)必須能在試驗時已使用侵入性呼吸器。
- 您(的家人)必須試驗時是使用鎮靜劑中。

若您(的家人)有下列任一情況，您(的家人)將無法參加本研究計畫：

- 您(的家人)目前使用神經肌肉阻斷劑中。
- 您(的家人)有四肢麻痺之症狀。
- 您(的家人)的周邊神經或腦部嚴重受損。

如果您(的家人)的條件符合，並決定加入本研究且簽署這份同意書後，您(的家人)將被隨機分配到三種疼痛評估方法之中的任一組〔臉譜疼痛量表、行為疼痛量表、危急照護疼痛觀察工具〕。本試驗為隨機、單盲研究。隨機分配就是由類似擲骰子般的機率決定您(的家人)的分組，您(的家人)有相同的機率被分配到任意組。唯有研究測試人員知道您被分配的組別，您(的家人)不知道您(的家人)是被分配到哪一組。

此試驗將在您(的家人)的加護照顧期間，選取您(的家人)的 4 次疼痛評估作為實驗數據，全程研究將不干擾您(的家人)的所接受之正規照護。研究的介入措施即是您(的家人)於加護病房所接受的例行治療：眼睛護理以及抽痰。護理人員將於您(的家人)兩種介入措施之前後，使用您(的家人)所分配到的疼痛行為量表評估您(的家人)的疼痛程度。因此，每位受試者應有 4 個觀察值：即眼睛護理前、眼睛護理後、抽痰前與抽痰後。每次所需的時間大約 5 分鐘。

4.可能產生之副作用、危險及處理方法

本試驗只於您（的家人）需要做例行治療時，護理人員順做觀察和記錄您（的家人）的疼痛反應，無副作用、危險和不適的情形產生。

5.試驗預期效果

此研究工具的國外版本已經臨床試驗證實是一個用以評估意識不清且使用呼吸器的患者之可靠的量表，藉由您（的家人）的參與而使得本試驗獲得的資訊，在未來可能有助於提供無法表達之患者更理想的疼痛治療。

6.其他可能之治療方式及說明

目前全國醫療院所通用於評估疼痛之評估工具，是使用臉譜疼痛量表。您（的家人）不一定要為了您（的家人）的症狀而加入本研究，您（的家人）也可以選擇原有的評估方式。我們的護理師會與您（的家人）討論這些檢查評估方式。

7.試驗進行之禁忌或限制活動

無。

8.機密性

雙和、萬芳及北醫附設醫院將在法律上所規範的程度內將您（的家人）的資料視為機密，您亦了解計劃研究團隊、衛生署、臺北醫學大學暨附屬醫院聯合人體研究倫理委員會與您（的家人）所在之各參與試驗醫院人體試驗委員會皆有權檢視您（的家人）的資料，亦會遵守保密之倫理。

對您（的家人）在研究中得到的檢查結果及醫師診斷，研究人員將以一個研究的號碼會取代您（的家人）的姓名來收集資料。除了上述機構依法有權檢視外，我們會小心維護您（的家人）的隱私。試驗結果即使發表，您（的家人）的身分仍將保密。

9. 試驗之退出與中止

您可自由決定是否參加本試驗，並於試驗過程中可隨時撤銷同意，退出試驗，不須任何理由，且不會引起任何不愉快或影響其日後醫師對您（的家人）的醫療照顧。此外，您並已充份了解試驗主持人亦可能於必要時中止該試驗之進行，但您（的家人）的醫師對您（的家人）的醫療照顧將不會造成影響。

10. 試驗之損害賠償與保險

- (1) 如依所訂臨床試驗計劃使用的疼痛評估工具，而引致不良反應或相關傷害發生時，均由臺北醫學大學負全部損害賠償責任。如依本研究訂試驗計劃因而引發之不良傷害，請立即通知您（的家人）所在_____醫院的醫師，_____醫院將提供您（的家人）專業醫療照顧。
- (2) 除法定賠償及醫療照顧外，本研究不提供其他形式之補償。若您（的家人）不願意接受這樣的風險，請勿參加試驗。
- (3) 您不會因為簽署本同意書，而喪失您（的家人）在法律上的任何權利。
- (4) 本試驗未投保責任保險。

11. 受試者權利與義務

- (1) 所有臨床試驗有關費用均由本研究計劃負擔。
- (2) 受試者參加本試驗無額外報酬。
- (3) 試驗過程中，與您（的家人）的健康或是疾病有關，可能影響您（的家人）繼續接受臨床試驗意願的任何重大發現，會即時提供給您（的家人）。
- (4) 如果您（的家人）現在或於研究期間有任何問題或狀況，請不必客氣，可與本計畫協同主持人/研究護士熊乃歡聯絡(電話：0928569093)。
- (5) 如您（的家人）在研究過程中對您（的家人）的權益有疑義或懷疑因參與研究受害時，請隨時與臺北醫學大學暨附屬醫院聯合人體研究倫理委員會聯絡(電話:(02) 27361661 轉 7198 或電子郵件信箱: tmu-jirb@tmu.edu.tw)

12. 簽章

受試者法定代理人或有同意權人聲明

以上的資訊已經向我說明，我有機會詢問此計畫的有關問題，我已了解且同意我所法定代理或行使同意權者參與此項研究計畫，同意書副本已交付。如果我以後有問題，我可與本計畫協同主持人/研究護士熊乃歡聯絡。

法定代理人姓名（正楷）_____（如適用）

簽 名 _____

日 期 _____

如您不是受試者或其法定代理人，但因事實需要，受試者或其法定代理人（暫時）無法簽署本同意書而需由您代簽。請用正楷書寫您的姓名，並指出您與受試者的關係：

姓名（正楷）_____

關 係 _____（有同意權之人為配偶或同居之親屬）

身份證字號 _____

聯 絡 電 話 _____

通訊地址 _____

簽 名 _____

日 期 _____

研究者聲明

我保證我本人或我的研究團隊中的一位成員（已獲授權進行本步驟的代表），已經對上述人士解釋過本研究，包括本研究的目的、程序與參加本研究可能的相關危險性和效益，以及目前可行的替代治療。所有被受試者之法定代理人或有同意權人提出之疑問，均已予以答覆。

計畫主持人/協同主持人 姓名（正楷）_____

簽 名 _____

日 期 _____

解釋同意書之研究人員 姓名（正楷）_____

簽 名 _____

日 期 _____

口頭同意之見證

(若受試者之法定代理人或有同意權者無法閱讀上述內容，而係經由研究人員口述說明，需有另一見證人在場)

茲證明計畫主持人及研究人員已完整地向簽署者解釋本研究的內容。

見證人 姓名（正楷）_____ (研究相關人員不得為見證人)

身份證字號 _____

聯 絡 電 話 _____

通 訊 地 址 _____

簽 名 _____

日 期 _____

(5)

Cover letter and Consent for patients

Version 1.3 31/07/2011

臺北醫學大學暨附屬醫院聯合人體研究倫理委員會

TMU-Joint Institutional Review Board 

焦點訪談參與量表測試之護理人員知情同意書

我們邀請您參加本研究，此份同意書提供您本研究相關資訊，計畫主持人或研究人員將為您詳細說明並回答相關問題。

計畫編號	無	IRB 編號	
計畫名稱	分析並比較疼痛行為量表中文版本之信度與效度		
研究成員		電話/分機	e-mail
主持人	林乾閔醫師	(02)2249-0088#8120	m513092004@tmu.edu.tw
協同主持人	吳忠哲醫師	(02)27372181#3918	dr.jcwu@gmail.com
協同主持人	陳淑美醫師	(02)29307930#6942	nschenis@gmail.com
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執行機構/單位	雙和醫院 神經外科 台北醫學大學附設醫院 神經外科 萬芳醫院 神經外科 英國愛丁堡大學 護理研究所		
計畫執行期限	約 1 年 0 月		
計畫簡述	本研究將發展兩種由法國學者 Payen 及加拿大學者發展出來的新型疼痛行為評估量表之中文版本:疼痛行為量表(BPS)與危急照護疼痛觀察量表(CPOT)。他們的原理基於人類對疼痛的刺激會產生全身的行為改變，以了解患者的疼痛程度。並在測試兩量表與現行疼痛評估工具:臉譜疼痛量表(FRPS)之效度與信度後，再深入訪談專家以了解他們的可行性與推廣時之困境。預計於 2011 年 5 月至 2012 年 4 月間，在臨床收集個案之數據以評估量表的信度與效度。爾後，2011 年 10-12 月間，選擇台灣醫療院所 20 位曾參與量表測試之專業護理人員進行焦點團體訪談。		
研究目的	您參與本研究的目的為協助了解各類疼痛評估工具 BPS、CPOT 及 FRPS 之可行性與臨床使用情形，在您的工作上並不會有個別性的差異也不影響您原有的職務。本研究目的在發展國外已獲證實的兩個完整且有系統的疼痛行為量表之中文版本，並藉由試驗檢測其信度及效度。期望使加護病房重症患者在無法表達其疼痛時，醫護人員可使用客觀的疼痛評估工具，了解患者的疼痛程度，進而讓其獲得良好的疼痛處理。		

受訪者之篩選條件	<p>納入條件(符合下列條件者，適合參加本研究)</p> <ol style="list-style-type: none"> 1. 年齡 20 歲以上 2. 曾參與疼痛行為量表以及危急照護觀察工具測試之護理人員 <p>排除條件(若有下列情況者，不能參加本研究)</p> <ol style="list-style-type: none"> 1. 拒絕受訪者。
研究方法與程序	<p>整個研究期間大約 12 個月。第一階段預估 360 人次參與量表試驗；第二階段，目標訪談 20 位於台灣各醫療院所曾參與量表測試之護理人員，以了解三種疼痛量表在臨床上的使用情形。三院預計收錄 5-6 人參加。由計劃主持人，一位研究者為觀察者，以系統文獻查證對疼痛行為量表之發展結果做為參考設計半結構之大綱，進行約一小時焦點團體訪談；並以錄音方式進行資料之收集。所收集之錄音檔再打字轉換成文字檔以進行分析。所有的資料以不記名方式，將在編碼後輸入電腦，以統計軟體分析並以整體資料呈現。</p>
受訪程序可能產生之不便及處理方法	<p>參與本研究受測者接受問卷調查並不會有不適情形及潛在性的傷害發生。若因會談或詢問問卷時間冗長，讓您身心感到不適，請隨時與研究主持人或研究人員連絡，尋求說明或協助。您也可隨時提出退出本研究，我們將會尊重您意願。</p> <p>部分訪談內容需要錄音或錄影，以確保資料之完整性。您是否同意訪談時進行錄音或錄影？ <input type="checkbox"/> 同意 <input type="checkbox"/> 不同意</p> <p>完成書面資料後，錄音帶或錄影帶將會被銷毀，所有資料將儲存於電腦中並設定密碼或保存在上鎖的檔案櫃中，任何可能暴露您個人隱私的資訊將予以保密，以一個研究的號碼取代您的姓名。</p>
研究預期效益	<p>本研究將完成一份適用於重症病患之英文版本疼痛行為量表的中文翻譯；並藉由您參與本研究，得以了解此新疼痛評估工具之可行性及其推廣時之困境，有助於臨床醫護人員面對具有困難表達其疼痛的重症病患時，能有更良好的評估工具以了解患者的疼痛程度，並進一步達成良好之疼痛處理。</p>
研究進行中受訪者應配合之事項	無
機密性	<ul style="list-style-type: none"> ● <u>您服務之醫院</u>(依本同意書適用範圍可能為台北醫學大學附設醫院或台北市立萬芳醫院或行政院衛生署雙和醫院)將在法律上所規範的程度上將您的資料與訪談內容視為機密，您亦了解計劃執行單位、衛生署與臺北醫學大學暨附屬醫院聯人體研究倫理委員會皆有權檢視您的資料，亦會遵守保密之倫理。 ● 對您在研究中得到的資訊，研究人員將以一個研究的號碼會取代您的姓名來收集資料。除了上述機構依法有權檢視外，我們會小心維護您的隱私。試驗結果即使發表，您的身分仍將保密。

補助與損害賠償	<ul style="list-style-type: none"> ● 參加訪談的補助:無 ● 受試者不必負擔參與試驗所需之費用。 ● 如依本研究訂臨床試驗計畫，而發生不良反應或損害，<u>您服務之醫院</u>(依本同意書適用範圍可能為台北醫學大學附設醫院或台北市立萬芳醫院或行政院衛生署雙和醫院)與試驗主持人願意提供專業醫療照顧及醫療諮詢。您不必負擔因方談而產生的不良反應或傷害之必要醫療費用。 ● 除法定賠償及醫療照顧外，本研究不提供其他形式之補償。若您不願意接受這樣的風險，請勿參加試驗。 ● 您不會因為簽署本同意書，而喪失在法律上的任何權利。 ● 本訪談未投保責任保險。
受訪者權利	<p>1.如果您現在或於研究期間有任何問題或狀況，請不必客氣，可與研究人員<u>熊乃歡</u>聯絡(電話：0928569093)。</p> <p>2.您提供的原始資料，僅限在<u>本研究計畫</u>資料庫中保管使用，不會連結到其他單位。如果別的單位或與社會大眾福祉有關的其它研究計畫需要您的資料，我們會再次徵詢您的同意，否則我們絕不會提供給他們。您的個人資料及隱私，會依我國相關法令獲得保障。</p> <p>3.如果您在研究過程中對您的權益有疑義或懷疑因參與研究而受害時，請隨時與臺北醫學大學暨附屬醫院聯合人體研究倫理委員會聯絡（電話：(02) 27361661 分機 7198 或電子郵件信箱：tmu-jirb@tmu.edu.tw)。</p>
研究之退出與中止	<p>您可自由決定是否參加本試驗，並於訪談過程中可隨時撤銷同意，退出訪談，不須任何理由，且不會引起任何不愉快或影響其日後您在醫院的職務以及任何相關事務。此外，您並已充份了解試驗主持人亦可能於必要時中止該訪談之進行，但您的主管對您的職務將不會造成影響。</p>
解釋同意書人	<p>(於本計畫中擔任：<input type="checkbox"/>主持人<input type="checkbox"/>協同主持人<input type="checkbox"/>研究人員)</p> <p>本人已詳細解釋本計畫中上述研究方法的性質與目的，及可能產生的危險與利益，並已回答受訪者之疑問。</p> <p>解釋同意書人簽名：_____ 簽名日期：____年__月__日</p>
受訪者	<p>經由說明後本人已詳細瞭解上述研究方法及可能產生的危險與利益，有關本研究計畫的疑問，亦獲得詳細解釋。本人同意並自願參與本研究，且將持有同意書副本。</p> <p>受訪者簽名：_____ 簽名日期：____年__月__日</p>
計畫主持人	<p>_____ 簽名日期：____年__月__日</p>

本同意書一式二份，雙方完成簽署後，各執一份留存。